In December 2017, DePuy Orthopaedics, Inc. voluntarily recalled the SIGMA® HP PFJ Cemented Trochlear Implant, which is a standalone component of the partial knee system. This decision was based on elevated revision rates observed as part of the company’s post market surveillance process. Further distribution or use of the affected implants has ceased, and the product is now discontinued. The company recommends that surgeons use alternative implants or consider a total knee replacement.

This surgical technique is available for historical information, if needed, for your patients who currently have a SIGMA HP PFJ Cemented Trochlear Implant. DePuy Orthopaedics, Inc. is not recommending prophylactic revision in the absence of symptoms. The company recommends that surgeons discuss potential clinical implications and risks with symptomatic patients who received the affected implants.
SIGMA® High Performance Partial Knee
Patello-Femoral Joint Surgical Technique
Table of Contents

**Pre-Operative**

- Patient Considerations 2
- Third Generation Considerations 3
- Pre-Operative Assessment 4
- Pre-Operative Imaging 5

**Surgical Technique**

- Incision and Approach 7
- Patellar Resection 8
- Trochlea Preparation 10
- Finishing Bone Preparation 15
- Trial Assessment 17
- Preparation of Peg Holes 18
- Trochlea Implantation 19
- Patella Implantation 19
- Closure 20

**Appendices** 21

**Ordering Information**

- Implants 22
- Instruments 23

**Essential Product Information**

- Total and Unicompartmental Knee Prostheses 25
Introduction

Isolated patello-femoral arthritis is found in approximately 10 percent of those patients who have knee arthritis. Although in the “third generation,” the key to a successful Patello-femoral Arthroplasty (PFA) is the appreciation that it is NOT 1/3 of a Total Knee Replacement (TKR). It remains extremely important to understand the fine points of soft tissue balancing specific to a patello-femoral arthroplasty, which are different from the soft tissue balancing of the patello-femoral (PF) portion of a TKR.

PFA is appropriate for patients with disabling end-stage primary or secondary (i.e., post-traumatic or dysplasia with chronic patellar static subluxation) osteoarthritis that is isolated to the patello-femoral compartment and refractory to conservative treatment. In these knees, the tibiofemoral compartment articular cartilage is intact and capable of bearing normal loads, the knee is stable, and asymptomatic except for the patello-femoral symptoms (Figure 1).

PFA is not appropriate for patients with active inflammatory arthritis, overt infection, significant chondrocalcinosis of the articular surface, symptomatic arthritic involvement of the tibiofemoral compartment, or patella infera. PFA is also not appropriate for unexplained patello-femoral pain not associated with osteoarthritis and in a complex regional pain syndrome (Figure 2).

PFA may not be appropriate for patients with marked patella alta, recurrent patellar instability, with or without patellar tilt, and chronic lateral subluxation of the patella. If present, the underlying pathology allowing the recurrent patella instability or chronic excessive lateral position of the patella will need to be corrected at the time of resurfacing, i.e., medial patello-femoral ligament surgery (Figure 3).
This third generation patello-femoral implant is purposely less constrained than earlier generations. It is designed to reduce wear, shear forces and the risk of loosening. The patella component is the same as the options available for the P.F.C.® SIGMA® Total Knee Replacement. However, the SIGMA® HP Partial Knee trochlear component is not the trochlea from the SIGMA TKR System. It was designed to meet the requirement of a PFA; it is narrower and more bone conserving. In addition, it allows the component to be either used in an inset or onset fashion and decreases overhang impingement that previously had been associated with post-operative anterior knee pain. As this design closely replicates the normal anatomy, soft tissue balancing is extremely important.

**Note:** Appreciation of the role of the medial and lateral patello-femoral ligaments in balancing the patella is emphasized.

To achieve an optimal result, it is necessary to reproduce normal patellar tracking with this minimally constrained anatomic design. Consideration should be given to counseling patients that, at times, post-operative muscle activation may in some cases cause subtle changes in tracking that could require further (staged) balancing.
After assessing patient considerations, the knee should be classified pre-operatively to allow optimal surgical planning:

**Isolated Patello-femoral Degenerative Joint Disease (DJD) with Normal Anatomy**

These patients will have isolated patello-femoral arthritis with no history of instability. They will typically have normal anatomy that can best be treated with an inset rather than an onset trochlear component. The patella resurfacing may be of the surgeon’s preference. The patient may be counseled that the failure mode will often be through tibiofemoral degeneration. In addition, patients should be advised that, if intra-operatively there is more tibiofemoral degeneration than expected, they could be treated with bicompartamental or total knee arthroplasty.

**Isolated Patello-femoral DJD with PF Dysplasia**

These patients will have dysplasia and isolated patello-femoral arthritis without a history of instability. They will have trochlear morphology typically best treated with an onset trochlear technique. They often have associated patella alta, which needs to be rechecked and treated as indicated. These patients typically do not have significant tibiofemoral compartment degeneration (Figure 4).

**Isolated Patello-femoral DJD with History of Instability**

Patients with isolated patello-femoral arthritis with a current or remote history of instability may have normal to severely dysplastic patello-femoral compartments with considerations as above. However, they present additional challenges. The most common history is one of dislocations in their youth followed by a period of no dislocations and finally a presentation of pain and arthritis. They may have had multiple surgeries including chondroplasty, tibial tuberosity osteotomy and medial soft tissue tightening and lateral release. Thus, they may have medial as well as lateral instability. Once the arthritic patello-femoral compartment is replaced with low friction components, old instability patterns may reappear in the post-operative setting if not addressed intra-operatively (as described in Appendix III). Please refer to that section before treating this complex patient.

**Isolated Patello-femoral Arthritis with a History of Trauma**

This category is historically included in discussions of patello-femoral degenerative joint disease treatment. However, post-traumatic problems may include instability from the trauma, or post-traumatic changes with or without a fracture. Those with post-traumatic arthritis after a fracture may have an enlarged irregularly shaped patella with bone incongruities that require special attention to positioning the patella component and managing the soft tissue scarring and ligament imbalances. The post-traumatic patients with arthritis, but without a fracture, may have had chondrocyte death from the impact and subsequent premature patella degenerative changes. Those with a history of post-traumatic instability would be assessed as noted above in the instability section.

**Examination**

After classification of the patello-femoral compartment by X-ray, it is important to review the specifics of the pre-operative examination:

1. **Patellar Tracking:** Should be observed while actively flexing and extending the knee when sitting and/or loaded against resistance or squatting if not too painful.
2. **Patellar Displacement:** Medial and lateral displacement of the patella is documented in trochlear quadrants from a central trochlear position. Excessive medial and lateral patholaxity may be noted and considered for intra-operative treatment.
3. **Patellar Tilt:** Inability to lift the lateral facet of the patella to neutral while the knee is in 20 degrees of flexion may be considered fixed tilt.
In the past, classic templating was used infrequently with PFA implants as compared to unicompartmental knee arthroplasty or TKR. However, pre-operative review of the bony anatomy and relative position of the patella to the trochlea may aid in the intraoperative determination of the position and sizing of the components. The following examinations are recommended:

**Weight Bearing Anterior/Posterior (A/P) View**

This will allow assessment of the tibial-femoral compartment and assess the size and shape of the patella as well as to determine post-fracture changes for bipartite patella. These observations do not exclude use of a patello-femoral arthroplasty, but will forewarn of potential problems. If there is evidence of joint space narrowing, osteophytes, or other signs of degenerative changes, this patient will not be a candidate for an isolated patello-femoral arthroplasty. This X-ray may be taken as an A/P standing erect or as an A/P in slight flexion. If there is a concern that the patient may have degenerative changes, both studies may be appropriate.

**True Lateral View**

A true lateral view (with matching of posterior femoral condyle contours) is essential for measurement of patellar height (Caton-Deschamps ratio below 0.8 is inferia and above 1.2 is alta, with the knee in 30 degrees of flexion), and extent of retropatellar degenerative changes. (Size and position of osteophytes, quality of bone with presence or absence of cysts, and re-evaluation of the tibiofemoral space.) It is also very useful for classification of trochlear morphology and tilt (Figures 5 and 6).

**Weight Bearing Anterior/Posterior View**

This view highlights the region of the tibiofemoral compartment most often involved with narrowing secondary to arthritis and supplements the A/P view. The tibiofemoral compartments may have normal joint spaces on one of these views and narrowing on the other. (Figures 7 and 8).
Axial View
This is very important for assessing the structure of the patella and its relationship to the trochlea. This should be a supine, low flexion angle (30 to 45 degrees) and a higher flexion view (50-60 degrees). While this view can suggest trochlear morphology (dysplasia), it should be appreciated that even with the axial and lateral views, trochlear dysplasia can be underestimated. (Figures 9a and b).

Applying the Imaging Studies
Direct intra-operative measurement is the standard for onlay patella sizing and positioning. However, the Merchant view will aid in pre-operative planning for the positioning and/or feasibility of an inset patella component. It is also useful in determining and planning for the treatment of bone deficiencies. The Merchant view, in conjunction with the Lateral view, is useful in determining if the morphology is within normal limits or has a degree of dysplasia. It is possible to pre-operatively determine if it will be best to consider insetting or onsetting the trochlear component, i.e., inset for more normal morphology and onset for more dysplastic morphology. In addition, the lateral view will allow measurement of patellar height of significant patella infera or significant patella alta. If either is present, they may require a tibial tuberosity osteotomy to assure appropriate contact of the patella in the trochlea during flexion and extension with full quadriceps activation.

CT and MRI
For knees with a physical examination or radiographic view that is even slightly suggestive of excessive lateral position of the tibial tuberosity, CT (Figure 10) or MRI (Figure 11) assessment of the tibial tuberosity to trochlear groove (TT–TG) distance will aid in the decision to normalize the tuberosity position through precise tibial tuberosity medialization. Note that these measurements may be obtained during any standard MRI or CT if the cuts include the tibial tuberosity.4
The skin incision is most often midline and long enough to obtain adequate exposure. It is usually longer with obesity and shortens with experience.

**Deep Soft Tissue Approach**

The knee may be entered by a medial or lateral parapatellar arthrotomy. With a medial approach, the Medial Patello-Femoral Ligament (MPFL) can be shortened (tightened) at closure. The standard medial capsular incision should begin near the superior border of the patella and extend distally along the medial border of the patella and patella tendon. A proximal extension of the incision is advised when first starting to use the procedure or if the patient is obese. Obviously, it is important not to harm the uninvolved articular cartilage and the meniscus. Alternatively, if the patient does not have MPFL patholaxity, and the primary soft tissue pathology is excessive lateral tightness associated with patellar tilt, the deep approach may be made laterally. This may be through a standard lateral parapatellar incision or the less widely known lateral lengthening approach. This lateral approach allows for direct treatment of patellar tilt and avoids the Vastus Medialis Oblique (VMO).

Once the joint is exposed, make a final assessment of the extent of arthritic damage in all three compartments and the suitability of the joint for patello-femoral arthroplasty. If the tibiofemoral compartments have chondrosis, various treatment options must be considered based on the extent and site of the involvement. These options include: proceed with patello-femoral arthroplasty, and transfer an osteochondral plug from the patello-femoral compartment to resurface a small focal defect; add a tibiofemoral unicompartmental component; or proceed to a TKR. This illustrates the importance of pre-operative planning and the patient informed consent process.
**Onset Technique**

Preparation of the patella can be performed before or after the trochlear preparation. The advantage to a patella first approach is that the decrease in patellar thickness allows subluxation of the patella into the gutter for improved trochlear visualization. Carefully resect the fibrous tissue, fat and synovium from the patella to expose the margins of the patellar and quadriceps tendon attachments. Remove marginal osteophytes. With the knee in extension, complete visualization of the patella is possible without full eversion. The primary goal is good visualization.

Assess the thickness of the patella and calculate the level of bone resection with adjustments for asymmetry and bone loss (Figure 12).

The thickness of the resurfaced patella should be the same as the natural patella, understanding that in situations of bone loss the remaining patella bone should not be less than 12 mm. After resection, the patella thickness should be uniform in all quadrants: medial, lateral, superior, inferior. The resection surface should be parallel to the insertion of the quadriceps tendon. Some surgeons may prefer a freehand saw cut using the plane of the quadriceps and patellar tendons as a reference for the cut. This is acceptable if a reproducible flat cut with a uniform thickness (NOT thinner than 12 mm) is achieved. Thickness is assessed, and the goal is to normalize the composite thickness—not overstuff.

For those who prefer a guide to make the patellar resection, clear the patella as above. Attach the Patellar Clamp to achieve a uniform thickness post resection. Use the quadriceps and patellar tendons as references. Select a Patella Stylus that matches the thickness of the implant to be used (Figure 13).

The minimum depth of patella resection should be no less than 8.5 mm. However, when the patella is bone stock deficient, use the 12 mm remnant Patella Stylus (Figure 14) attached to the anterior surface of the patella to maintain a minimal residual thickness of 12 mm to avoid fracture (Figure 15).
Slide the appropriate size stylus into the saw capture of the Resection Guide. To achieve a “normal composite” thickness of the patella plus implant, the minimum composite thickness should be 23 mm for a size 41 mm implant. For all other sizes of patella, the minimum should be 20.5 mm. Place the leg in extension and position the patella Resection Guide with the Sizing Stylus against the posterior cortex of the patella with the serrated jaws at the superior and inferior margins of the articular surface. The jaws should be closed to firmly engage the patellar margins (Figure 16). Tilt the patella laterally to an angle of 40 to 60 degrees. Remove the stylus and perform the resection using an oscillating saw through the saw capture and flush to the cutting surface (Figure 17).

In cases where there is bone loss (typically lateral) after the cut is finished, it may be possible to slightly medialize a smaller patella implant to a region with better bone stock. The surgeon may also consider augmentation techniques. Measure the patella thickness, calculate the new implant plus bone thickness and recut as necessary to achieve the desired composite thickness. For patellar onset implants, the Drilling Guide is applied and the three fixation holes are drilled. Any eburnated bone may be drilled to improve cementation. The patella is then subluxed into the gutter and protected. A protective metal Patella Wafer can be hand placed on the resected surface to protect the patella bone bed or the bone may be protected with retractors.

**Inset Technique**

See the P.F.C. SIGMA Knee System Inset Patella Surgical Technique (Cat. No. SIG-086).
To appreciate the true bony architecture, remove all osteophytes from the intercondylar notch and from the lateral and medial ridges of the trochlea. Select the proper implant size using the Transparent Trial template so that the distal tip sits 2 mm above the apex of the intracondylar notch roof (Figure 18) and the width does not exceed local anatomy. The superior border of the trial will lie just above the superior articular surface of the trochlea (Figure 19). Based on the size of the Transparent Trial template, select the appropriate size of the Anterior Block. This will allow the operating room technician to assemble the Anterior Cutting Guide during the Distal Pilot Drilling.

Place the tip of the Distal Pilot Drill 7 mm proximal to the apex as to allow the final socket placement 2 mm above this apex (Figure 20).

Do not use excessive force on the collared level, as this will deform (compress) the local cartilage, causing the socket to be formed too deeply and thus excessively inset the tip of the final implant.

**Note:** The point of the Distal Pilot Drill is 7 mm above the apex of the roof of the notch.
Place the distal peg of the Anterior Block in the above created socket. The distal lip on the peg is placed flush with the remaining 2 mm of articular cartilage immediately above the notch (Figure 21).

With the Sizing Arm attached to the Anterior Cutting Block, use correct sizing so that it extends proximally beyond the articular cartilage of the native trochlea, as the implant is designed to extend proximal to the native trochlea to accept a mild degree of patella alta (Figure 22).

The Anterior Block will largely dictate the final trochlear implant position, so it is essential to carefully find the proper orientation. There is not uniform agreement among surgeons on anatomic references for trochlear component placement. Some surgeons may choose to refer to anatomic femur angle, epicondylar axis, Whiteside’s line, etc. The goal is a correctly positioned trochlea to normalize the kinematics of the patellofemoral compartment.

1. Distal tip is flush with surrounding cartilage. This is set by the initial stepped Drill Bit socket.

2. Distal triangle of the trochlear implant is either flush or slightly recessed.

Note: The implant's anterior surface medial/lateral radius of curvature is symmetrical to match the patellar component and the native trochlea is not (the medial trochlea and medial femoral condyle extend more distally than the lateral side); therefore, there will always be a slight mismatch between the implant and native trochlea. As per No. 1 above, the distal aspect is set flush by the stepped Drill Bit. The medial and lateral aspects of the distal triangle are fine-tuned by slight varus/valgus or rotational movements of the jig. Most typically, the movement to create a flush fit is to rotate the proximal portion of the block medially. This is compensated for by the lateral angle of the proximal aspect of the trochlea component required for right and left knee geometry.
3. The proximal final implant is not proud and does not notch the femur. Achieve this by placing the Sizing Arm flush with anterior cortex of the distal femur as this sets the proximal trochlea final component flush without notching or sitting proud.

4. Rotation is selected that does not cause lateral impingement (Figure 23), excessive internal rotation (Figure 24) or decreased lateral restraint (excessive external rotation). With a normal anatomic trochlea, the medial and lateral aspects of the Anterior Block are matched to the local native trochlear margins using a flat surface; e.g., a small osteotome, set on the medial and lateral cutting guides (Figure 25). With the flat reference placed on the articular cartilage of the normal trochlea margins, this will result in the final component being placed flush on both sides. A laser-etched line is present on the block that shows the component position and can be referenced by visualizing the skyline of the trochlear condyles. During this planning exercise, the extent of varus/valgus positioning is reassessed and adjusted to assure there is no medial (rare) or lateral (more likely) overhang. If this occurs, reassess steps No. 2 through No. 4 and, if necessary, downsize the block. Next assess the medial and lateral extent of the planned vertical cuts to confirm they will be inboard to the articular margins and allow for an inset technique, if planned.
With trochlear dysplasia, a properly sized trochlea implant may extend medially or laterally so there is no remaining native cartilage after the anterior cut. In this case, rotation is set by paying attention to the distal anterior femur and matching the medial and lateral distal triangle margins. In most dysplastic situations, there is a trochlear entrance “boss” and excessive central trochlear bone/cartilage more prominent than medial and/or lateral dysplasia. Locally, with the knee in 90 degrees of flexion, the trochlear anterior cut may be secondarily checked with Whiteside’s line and the distal tibia; the anterior cut is roughly perpendicular to these references.

With the Anterior Block in proper position, secure the block with Threaded, Headed pins (one through the pilot socket hole and the other oblique; Figure 26). The Reference Guide can be used to reconfirm the exit plane of the cut so that the femoral bone will not be notched.

Use a sagittal saw blade to make vertical medial and lateral cuts with care to stay in the plane of the block (do not dive into the femur; Figure 27).

Use an oscillating saw blade to make the anterior cut (Figure 28).
Remove the pins and block. The amount of bone cut removed is designed to be the same as the final component thickness, except for minor milling centrally.

Engage the above selected size of the Finishing Guide so the depth stop on the distal foot is flush with the distal remaining articular cartilage just above the roof of the notch—take care not to force it deeper or to allow it to remain proud as this sets the depth of the final bone resection (Figure 29). Secure the guide with Threaded, Headed Pins starting with the proximal pins first (Figure 30).
Finishing Bone Preparation

The Cutting Bit (Cat No. 2024-61-010) is intended for use with standard high speed burring systems. The plastic washer on the cutter is set to remove bone to full depth required for the final implant. Take special care when starting the Cutting Bit into hard bone. It is advised that you stabilize your hand and enter the bone with the edge of the Cutting Bit (Figure 31) and not the flat end of the Cutting Bit.

The plastic washer must lay flat on the Finishing Guide to resect the proper amount of cartilage and bone (Figures 32 and 33).

**Note:** Carefully follow the internal track of the Finishing Guide. The cutting bit is only used on the track and NOT freehand at this point.
Place the Transparent Trial of the proper size on the trochlea (Figure 34).

The Transparent Trial has the same shape and size as the implant with markings showing patella tracking and the anatomical axis of the femur. The trial does not have pegs or the cement pocket geometry. Some additional bone clean up with the cutter or cartilage fraying at the margins with a rongeur may be necessary. Recheck the cavity with the trial to assure proper fit and alignment. The goal is to set the distal tip flush with surrounding cartilage, the distal triangle flush on both sides (or one flush and one slightly recessed) and provide a smooth transition for the patella proximally (Figure 35).

**Note:** The rounded margins of the trial and final implant can visually appear flush, yet may be slightly proud. To assure the trial and thus the final implant are flush, use the flat end of an osteotome to bridge across the face of the trial component to prove the trial is flush or slightly recessed onto the surrounding articular cartilage. It should prove the trial is flush or slightly recessed (Figure 36).
If the patella has not yet been prepared, prepare it as described earlier in this technique.

With the patella and trochlea trials in place, move the knee through range of motion and assure:

1. Smooth transition of patella from trochlea into the notch (Figure 37).
2. Smooth entrance of the patella into the trochlea component on extension (Figure 38).
3. With proximal traction on the quadriceps tendon, the patella component should be engaged on the trochlea component in the fullest extension possible for the knee (if patella alta is present that does not allow patella component contact with the trochlea component at full extension, tibial tuberosity distalization will be necessary).
4. Assure no abrupt medial or lateral movements occur.
5. Assess for tilt (will also need attention during closure).
6. Assess medial and lateral displacement (in certain advanced cases this may require temporary suturing and final tuning after the components are cemented).
The next step is to drill the peg holes.

Assemble the Drill Guide onto the Metal Trial by inserting the lock rod through the center hole of the Drill Guide and screwing it into the center hole of the Metal Trial. Be sure to position the Drill Guide correctly for “left” or “right” components (Figure 39).

When the assembly is complete (Figure 40), use the Peg Drill to drill the distal peg hole first. After the first hole is drilled, insert a Stabilizing Pin (Figure 41) into that hole.

Drill the second hole and insert a second Stabilizing Pin (Figure 42). Drill the third hole and remove the assembly.
Trochlea Implantation

Drill any area of eburnated bone to improve cementation. Clear the bone of debris, blood and fat. Apply cement to the posterior surface of the trochlear prosthesis and also apply cement packed with finger pressure to the prepared bone. Impact the component into the prepared cavity using the Impactor (Figure 43). Pay special attention to the alignment of the three pegs into the three fixation holes. Remove any extruded cement with a curette.

Patella Implantation

The patellar cut surface is thoroughly cleansed with pulsatile lavage. The protective metal Patella Wafer is removed if used. Apply cement to the cut surface and implant, then insert the component. Center the silicon O-ring over the articular surface of the implant and the metal backing plate against the anterior cortex, avoiding skin entrapment. When snug, close the handles and hold by the ratchet until polymerization is complete. Remove all extruded cement with a curette. Release the clamp by unlocking the locking switch and squeezing the handle together.

After the cement is cured, the patella is reduced and the patella implant tracking is reevaluated. An unrestricted range of motion and proper patellar tracking should be evident.
As will be common in many knees, the post-operative composite patello-femoral thickness is greater than pre-operatively (bone and cartilage loss have been restored with metal and plastic) even though the components are technically not too thick (true overstuffing). The new composite patello-femoral thickness relatively “stuffs the soft tissue envelope” that the knee has acquired over time. With flexion, soft tissue lengths change with the lateral side becoming tighter and the medial side more lax. In other words, even with a technically correct thickness, the new thicker composite will apply tension in the lateral soft tissues causing tilt during flexion. The typically required external rotation of a TKR to balance flexion/extension gaps is not duplicated in a patello-femoral arthroplasty (as the tibia was obviously not cut into relative valgus—the reason for TKR external rotation). Thus, it will be more common to have lateral tightness in flexion with a patello-femoral arthroplasty than a TKR and therefore lateral release, lateral subperiosteal recession or lateral lengthening will be necessary more often after patello-femoral arthroplasty than TKR. Closely monitor midterm post-operative axial radiographs to observe for this phenomenon.
APPENDIX I – Rehabilitation
Initial emphasis is on controlling swelling with compression and cooling while maintaining quadriceps function. Gentle range of motion is begun post-operatively on day one and progresses to 90 degrees by day two and full motion (or the limit of swelling) by week four. Weight bearing is as tolerated with protective support until quadriceps strength is sufficient for a safe and normal gait. Standard core proximal muscle strengthening, flexibility and quadriceps exercises are continued until the gait is normalized.

APPENDIX II – Distal Realignment
Some patients will have an excessive laterally positioned tibial tuberosity. This contributes to a lateral force vector that may not be compensated by proximal soft tissue balancing. If this is suspected, it is evaluated and measured with CT or MRI pre-operatively. The position of the tuberosity is measured relative to the trochlear groove (Tibial Tuberosity – Trochlear Groove or TT-TG distance). The radiologist can calculate this on either MRI or CT using the technique described by Shoettle et al. Normal values are in the range of 10 to 13 mm and grossly abnormal are over 20 mm. When the TT-TG is elevated pre-operatively, and lateral tracking persists after appropriate medial and lateral soft tissue balancing, the tuberosity is osteotomized and transferred medially to normalize the position (10 to 13 mm), but not to overmedialize. The technique is not unique to patello-femoral arthroplasty and will require reassessment of the proximal medial and lateral balancing with the tuberosity in the new position.

APPENDIX III – Medial Proximal Soft Tissues
Newer appreciation of the role of the medial patello-femoral ligament (MPFL) in maintaining a checkrein to lateral displacement allows for selective shortening (tightening) of that structure rather than non-anatomic global medial reeifing or VMO advancement. Recurrent lateral patella instability will require assessment of the MPFL damage. If it is adjacent to the patella, direct shortening at that site is logical. If the pathology is at the femoral attachment, reattachment may be possible. If the damage is diffuse or poorly defined, then a formal MPFL reconstruction may be necessary. To avoid drill holes in the patella, an option for fixation is a suture anchor technique.

Caution: If the patient has had a suspected remote lateral instability episode, it is possible that in recent years the friction of the arthritis has prevented instability. The medial tissues may seem adequate to allow shortening of the MPFL at the patella, but over time with the new low friction patello-femoral arthroplasty, natural lateral vector forces may stretch the compromised tissues and allow lateral subluxation.

1. With this history, be very vigorous in testing the medial structures. If there is question of adequacy, augment or reconstruct the MPFL.

2. Discuss this possibility with the patient pre-operatively as a possible occurrence, so if additional MPFL surgery is required in the post-operative setting, the patient will understand the difficulty of balancing the soft tissues in a nonfunctional situation (OR vs. ambulation and activities of daily living).

APPENDIX IV – Lateral Proximal Soft Tissues
As previously noted, the tendency will be for lateral soft structures to become tighter in flexion than medial soft tissue structures. The goal is for an even balance. As the thickness of a laterally worn patello-femoral compartment will be normalized, pre-operatively it can be appreciated that more length will be needed in the lateral structures. If the medial structures have no history of injury, then a lateral approach would appear logical to avoid insult to the VMO. This can be accomplished by a titrated lateral release (release only enough to allow reversal of tilt as opposed to a set amount of release), which remains open at the end of the case. Alternatively, a lateral lengthening approach will allow closure of the joint. Additionally, lateral structures not only contribute to limiting excessive medial displacement but also participate (somewhat counterintuitive) in limiting excessive lateral displacement.

For knees approached through a medial arthrotomy, both of these lateral-relaxing techniques may be applied with special attention to maintaining patellar blood supply. Alternatively, for those with low levels of expected lateral tension (for example, a normal appearing patello-femoral compartment radiographically that has extensive chondrosis/degeneration—as in the case of many bicompartamental arthroplasties where the predominant pathology is the patellofemoral compartment) a patellar subperiosteal recession may be sufficient.
## Ordering Information

### Implants

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Size</th>
<th>Side</th>
</tr>
</thead>
<tbody>
<tr>
<td>1024-03-100</td>
<td>Trochlea, Left, Size 1</td>
<td>29.6 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-03-200</td>
<td>Trochlea, Left, Size 2</td>
<td>31.6 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-03-300</td>
<td>Trochlea, Left, Size 3</td>
<td>33.8 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-03-400</td>
<td>Trochlea, Left, Size 4</td>
<td>36.2 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-03-500</td>
<td>Trochlea, Left, Size 5</td>
<td>38.7 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-04-100</td>
<td>Trochlea, Right, Size 1</td>
<td>29.6 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-04-200</td>
<td>Trochlea, Right, Size 2</td>
<td>31.6 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-04-300</td>
<td>Trochlea, Right, Size 3</td>
<td>33.8 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-04-400</td>
<td>Trochlea, Right, Size 4</td>
<td>36.2 mm</td>
<td>M/L</td>
</tr>
<tr>
<td>1024-04-500</td>
<td>Trochlea, Right, Size 5</td>
<td>38.7 mm</td>
<td>M/L</td>
</tr>
</tbody>
</table>
## Ordering Information

### Instruments

<table>
<thead>
<tr>
<th>Top Tray</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2024-65-100 Metal Trial 1L</td>
</tr>
<tr>
<td>2</td>
<td>2024-66-100 Metal Trial 1R</td>
</tr>
<tr>
<td>3</td>
<td>2024-65-200 Metal Trial 2L</td>
</tr>
<tr>
<td>4</td>
<td>2024-66-200 Metal Trial 2R</td>
</tr>
<tr>
<td>5</td>
<td>2024-65-300 Metal Trial 3L</td>
</tr>
<tr>
<td>6</td>
<td>2024-66-300 Metal Trial 3R</td>
</tr>
<tr>
<td>7</td>
<td>2024-65-400 Metal Trial 4L</td>
</tr>
<tr>
<td>8</td>
<td>2024-66-400 Metal Trial 4R</td>
</tr>
<tr>
<td>9</td>
<td>2024-65-500 Metal Trial 5L</td>
</tr>
<tr>
<td>10</td>
<td>2024-66-500 Metal Trial 5R</td>
</tr>
<tr>
<td>11</td>
<td>2024-67-100 Transparent Trial 1L</td>
</tr>
<tr>
<td>12</td>
<td>2024-68-100 Transparent Trial 1R</td>
</tr>
<tr>
<td>13</td>
<td>2024-67-200 Transparent Trial 2L</td>
</tr>
<tr>
<td>14</td>
<td>2024-68-200 Transparent Trial 2R</td>
</tr>
<tr>
<td>15</td>
<td>2024-67-300 Transparent Trial 3L</td>
</tr>
<tr>
<td>16</td>
<td>2024-68-300 Transparent Trial 3R</td>
</tr>
<tr>
<td>17</td>
<td>2024-67-400 Transparent Trial 4L</td>
</tr>
<tr>
<td>18</td>
<td>2024-68-400 Transparent Trial 4R</td>
</tr>
<tr>
<td>19</td>
<td>2024-67-500 Transparent Trial 5L</td>
</tr>
<tr>
<td>20</td>
<td>2024-68-500 Transparent Trial 5R</td>
</tr>
<tr>
<td>21</td>
<td>2024-85-004 Bone File</td>
</tr>
<tr>
<td>22</td>
<td>2024-60-021 Stabilizing Pin</td>
</tr>
<tr>
<td>23</td>
<td>2024-60-020 Peg Drill</td>
</tr>
<tr>
<td>24</td>
<td>2024-63-000 Drill Guide</td>
</tr>
<tr>
<td>25</td>
<td>2024-85-005 Impactor</td>
</tr>
<tr>
<td>26</td>
<td>96-6515 Sp2 Pin Puller</td>
</tr>
</tbody>
</table>
Ordering Information

Instruments

Bottom Tray

1 2024-73-100 Anterior Block Sz 1L 16 2024-61-300 Finishing Guide 3L
2 2024-74-100 Anterior Block Sz 1R 17 2024-62-400 Finishing Guide 4R
3 2024-73-200 Anterior Block Sz 2L 18 2024-61-400 Finishing Guide 4L
5 2024-73-300 Anterior Block Sz 3L 20 2024-61-500 Finishing Guide 5L
6 2024-74-300 Anterior Block Sz 3R 21 2024-80-011 Sizing Arm 1-2
7 2024-73-400 Anterior Block Sz 4L 22 2024-80-012 Sizing Arm 3-4
8 2024-74-400 Anterior Block Sz 4R 23 2024-80-013 Sizing Arm 5
9 2024-73-500 Anterior Block Sz 5L 24 2024-80-004 Distal Pilot Drill
10 2024-74-500 Anterior Block Sz 5R 25 9505-02-071 Power Pin Driver
12 2024-61-100 Finishing Guide 1L 27 2024-99-111 System Handle
13 2024-62-200 Finishing Guide 2R 28 9505-02-072 Drill Pins
14 2024-61-200 Finishing Guide 2L 29 9505-02-089 Threaded Pins Headed
15 2024-62-300 Finishing Guide 3R 30 86-9117 Steinmann Pins
Total and Unicompartmental Knee Prostheses

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, posttraumatic 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 degrees) 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: 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.
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 post-operative 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.
References