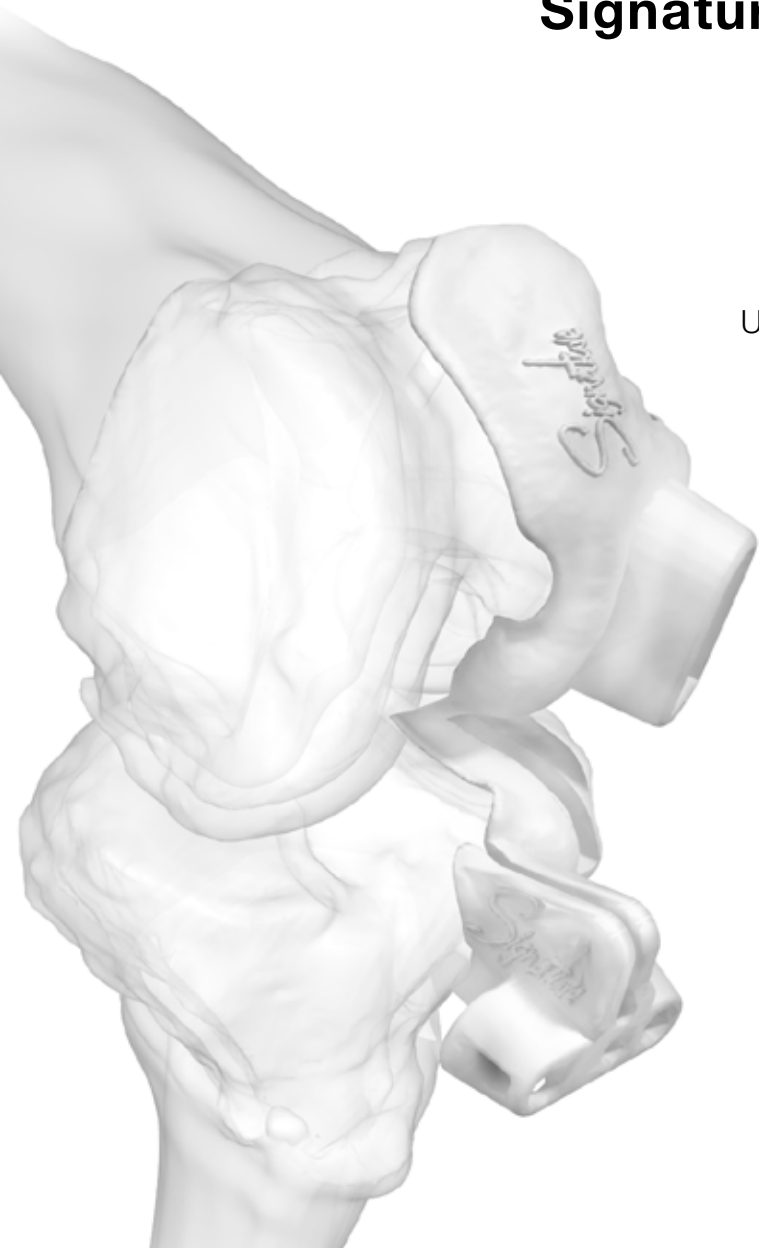


Signature™ Personalized Patient Care*

Surgical Technique Addendum

Oxford® Partial Knee

Utilizing Phase III and Microplasty® Instrumentation



BIOMET®

One Surgeon. One Patient.®

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally-invasive surgical technique, advanced biomaterials, or a custom, patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

Signature™ Personalized Patient Care

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In addition to the Oxford® Partial Knee this surgical technique addendum may also be used for the medial Vanguard® M Partial Knee.

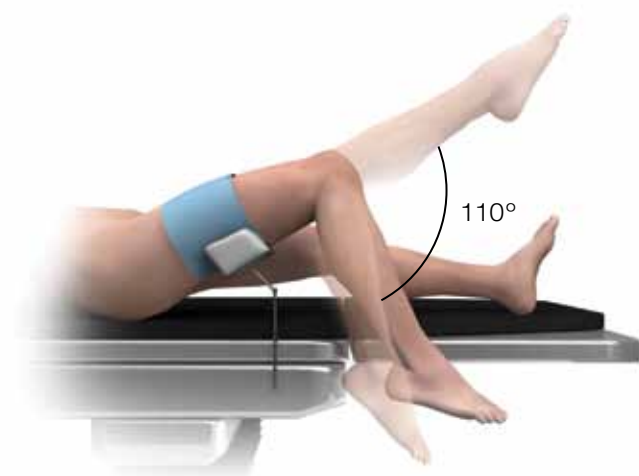


Figure 1



Figure 2

Positioning the Limb

Inflate a thigh tourniquet and place the draped leg on a thigh support, with the hip flexed to about 30 degrees and the leg dependent. The knee must be free to flex fully and the leg should hang with the knee flexed about 110 degrees. The thigh support must not be placed in the popliteal fossa as this will increase the risk of damage to the popliteal vessels (Figure 1).

Incision

With the knee flexed to 90 degrees, make a medial parapatellar skin incision from the medial margin of the patella to a point 3 cm distal to the joint line (Figure 2). Deepen the incision through the joint capsule. At its upper end, the capsular incision should extend proximally about 2 cm into the vastus medialis. It should pass around the

patella and down beside the patella tendon. The anterior surface of the medial tibial plateau should be exposed.

Excise part of the retropatellar fat pad and insert retractors into the synovial cavity. The ACL can now be inspected to ascertain that it is intact. (Absence of a functioning ACL is a contraindication. If this is found, the operation should be abandoned in favor of a total knee replacement).

Note: The Signature™ femoral and tibial partial knee arthroplasty (PKA) guides were designed to register off the osteophytes. Therefore, do not remove the osteophytes.

Note: The MRI-based Signature™ femoral and tibial PKA guides were designed to replicate the preoperative surgeon-approved plan. Final component position should be validated intraoperatively when the capsular soft tissues may be appropriately assessed.

This surgical technique is utilized by Mr. Chris Dodd, F.R.C.S., Roger Emerson Jr., M.D., Adolph Lombardi Jr., M.D., David Mauerhan, M.D. and Prof. David Murray, F.R.C.S. Biomet as the manufacturer of medical devices does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.



Figure 3



Figure 4

Signature™ Femoral Guide Registration

Note: The Signature™ femoral guide was designed to register on the osteophytes. Therefore, do not remove the osteophytes prior to guide placement.

Flex the knee to 90 degrees. Using methylene blue, draw a line down the center of the medial condyle.

With the knee in extension, place the Signature™ femoral guide under the incision and quad tendon anteriorly past the point of planned registration. Rotate the guide posteriorly then laterally, while flexing the knee to approximately 90 degrees.

Note: Flexing beyond 90 degrees may cause the patella tendon to force the guide out of position. If necessary, use a patella retractor and/or decrease amount of flexion to allow for proper fit.

Register the guide in a fluid motion from anterior to posterior, then medial to lateral to lock the guide onto the medial condyle, condylar notch and the anterior medial ridge. The guide should register flush against exposed bone and cartilage without soft tissue impingement. Validate proper registration utilizing the drill guide window. This can be confirmed by looking into the drill guide window and verifying the position of the line. If the line is not central adjust the guide position (Figure 3). Additionally, retractors may be used to assess guide registration peripherally.

Once proper registration is achieved, insert the appropriate size femoral drill guide into the Signature™ femoral PKA guide (Figure 4). Only the appropriately sized femoral drill guide will fit properly within the Signature™ guide. When seated properly, only the top etched line on the tapered portion of the drill guide should be visible.



Figure 5

Signature™ Femoral Guide Registration (continued)

Note: Varus/valgus and flexion alignment can be evaluated before drilling by sliding the femoral alignment checker onto the femoral drill guide and inserting an EM rod through the alignment hole (Figure 5). If indicated alignment does not match the plan or is unacceptable, **Do Not Drill**. This could indicate improper guide registration. Check for proper guide registration or revert to standard instrumentation to complete surgical technique.

Pass the 4 mm drill through the anterior hole. Drill into the bone to its depth stop. Leave the 4 mm drill in place and advance the 6 mm drill through the posterior hole in the femoral drill guide until its depth stop. Remove the 4 and 6 mm drills, femoral drill guide and the Signature™ femoral PKA guide from the joint.



Figure 6



Figure 7

Femoral Saw Cut

Insert the posterior resection guide into the drilled holes and tap home (Figure 6).

Insert a retractor to protect the MCL. Using the 12 mm broad sagittal saw, excise the posterior facet of the femoral condyle. The saw blade should be bent slightly by dropping the saw to ensure it is guided by the underside of the posterior resection guide (Figure 7). Take care to avoid damage to the medial collateral and anterior cruciate ligaments.

Remove the guide with the slap hammer, taking care not to distort the drill holes. Remove the bone fragment.

There is now good access to the back of the joint, and any remnants of the medial meniscus should be removed. In the region of the MCL, a small cuff of meniscus should be left to protect the MCL from the tibial component. The posterior horn should be completely removed.



Figure 8



Figure 9



Figure 10

First Milling of the Condyle

Insert the 0 spigot, which has the thickest flange, into the large posterior drill hole and tap it until the flange abuts against the bone (Figure 8).

Note: The 0 spigot is designed to remove sufficient bone to allow the femoral component to seat. This amount varies with the degree of arthritic erosion of the condyle.

By extending the knee slightly and retracting the soft tissues, maneuver the spherical cutter onto the spigot (Figure 9) and into the wound so that the teeth touch the bone (Figure 10). Take care to avoid trapping soft tissues.

When milling, push firmly in the direction of the spigot axis, taking care not to tilt the tool. Mill until the cutter will no longer advance.

If in doubt, continue to mill. There is no risk of over-milling.



Figure 11

Remove the mill and the spigot and trim off the bone protruding from the posterior corners of the condyle that lie outside the periphery of the cutting teeth (Figure 11). Do not damage the flat posterior surface of the condyle.

All osteophytes may now be removed from the medial margin of the medial femoral condyle and from both margins of the intercondylar notch. The assistant extends and flexes the knee, moving the incision up and down, allowing the various osteophytes to come into view.

With a narrow chisel (6 mm), remove the osteophytes from beneath the medial collateral ligament and from the posterolateral margin of the medial condyle.

Note: No further milling should be performed until the tibial preparation is complete.

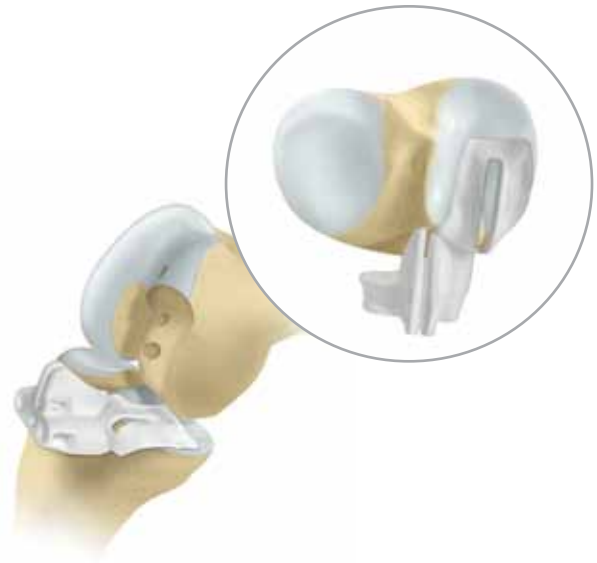


Figure 12

Signature™ Tibial Guide Registration and Resection

Expose the front of the tibia in the lower part of the wound from the tibial tubercle to the rim of the plateau.

Note: Do not 'release' any of the fibers of the medial collateral ligament.

Note: The Signature™ tibial partial knee arthroplasty (PKA) guides were designed to register off the osteophytes. Therefore, do not remove the osteophytes.

Note: The MRI-based Signature™ femoral and tibial PKA guides were designed to replicate the preoperative surgeon-approved plan. Final component position should be validated intraoperatively when the capsular soft tissues may be appropriately assessed.

Register the Signature™ tibial PKA guide onto the medial plateau and rotate downward until the guide makes contact anteriorly (Figure 12).



Figure 13



Figure 14

Signature™ Tibial Guide Registration and Resection (continued)

Signature™ tibial guide position may be validated by utilizing the guide window to assess plateau coverage and evaluate fit.

Insert the tibial drill guide into the Signature™ tibial PKA guide (Figure 13).

Note: Varus/valgus and slope alignment can be evaluated prior to drilling by sliding the tibial alignment checker onto the lateral side of the drill guide and inserting a rod through the alignment hole (Figure 14). If indicated alignment does not match plan the or is unacceptable, **Do Not Drill**. This could indicate improper guide registration. Check for proper guide registration or revert to standard instrumentation to complete surgical technique.



Figure 15

Drill a $\frac{1}{8}$ " trochar pin into the pin hole at the base of the vertical cut slot in the Signature™ patient-specific tibial PKA guide.

Pass $\frac{1}{8}$ " drill pins through two of the remaining taper holes in the Signature™ tibial guide (Figure 15).

Note: If utilizing Phase III Instrumentation pass the $\frac{1}{8}$ " drill pins through the two most medial taper holes.

Insert the saw blade into the cut slot before engaging power. Use a reciprocating saw to make the vertical tibial cut. Advance the saw vertically through the cut slot on



Figure 16

the Signature™ tibial PKA guide down until it rests on the surface of the $\frac{1}{8}$ " trochar pin (Figure 16). The pin will act as a saw stop.

Remove the $\frac{1}{8}$ " trochar pin from the pin hole at the base of the vertical cut slot, drill guide and Signature™ tibial guide. The two distal pins should be left in place.



Figure 17



Figure 18



Figure 19

Signature™ Tibial Guide Registration and Resection (continued)

Slide the tibial retractor onto the remaining $\frac{1}{8}$ " drill pins through the drilled pin holes. Once in position, validate varus/valgus and posterior slope alignment using tibial retractor (Figures 17 and 18).

Note: If utilizing Phase III Instrumentation, slide the tibial retractor onto the remaining $\frac{1}{8}$ " drill pins through the two lower holes.

Before making the horizontal cut, insert a medial collateral ligament (MCL) retractor. Ensure the retractor is between the saw and the MCL.

Use a 12 mm wide oscillating saw blade with appropriate markings to excise the plateau (Figure 19). Insert the captured or non-captured shim saw guide. Ensure the saw blade is run along the MCL retractor to completely cut the medial cortex. To cut the posterior cortex deepen the cut until the appropriate mark on the saw blade is aligned with the anterior cortex.



Figure 20

When the plateau is loose, lever it up with a broad osteotome and remove (Figure 20). Posterior soft tissue attachments may need to be cut with a knife. The posterior horn of the medial meniscus can now be removed.

The excised plateau will show the classic lesion of anteromedial osteoarthritis with eroded cartilage and bone in its mid and anterior parts and preserved cartilage posteriorly (Figure 21). Osteophytes around the edge of the plateau remain attached after its removal.



Figure 21

Use the excised plateau with the tibial templates to confirm the size of the tibial implant. Lay templates of the opposite side on the cut surface of the excised plateau to choose the component with the appropriate width.

Osteophytes on the tibial plateau in front of the insertion of the ACL and in the top of the notch must be removed to allow the fixed flexion deformity to correct. If there are large osteophytes around the patella they, should also be removed.



Figure 22

The thickness of bone removed from the tibia must be enough to accommodate the tibial template and a bearing at least 4 mm thick (3 mm is the smallest size available). To check that sufficient bone has been excised, insert the femoral trial, tibial template and a 4 mm feeler gauge (Figure 22).

Note: Whenever a feeler gauge is used to measure a gap, the retractors are removed. When left in, they have the effect of tightening the soft tissues, which artificially diminishes the gap.

If the 4 mm feeler gauge cannot be inserted or feels tight, more bone must be excised from the tibia. To do this,






remove the initial/0 mm shim from the guide. Resect off the surface of the guide without shim to remove 2 mm of additional bone.

Note: If utilizing Phase III Instrumentation, shift the tibial resection guide from the bottom row of holes to the top row in order to remove 3 mm of additional bone.

After additional resection, recheck the gap with the tibial template in place and at least a 4 mm feeler gauge.

See instrument platform surgical techniques for Equalizing and Confirming Flexion and Extension Gaps, Preventing Impingement, Final Preparation of the Tibial Plateau, Final Trial Reduction and Cementing the Components.

Instruments

Product	Part Number	Description	Size
	42-411400	Signature™ Alignment Rod	-
	42-411401	Signature™ Femoral Alignment Checker*	-
	42-411402	Signature™ Tibial Alignment Checker (Left)	-
	42-411403	Signature™ Tibial Alignment Checker (Right)	-
	42-411420	Signature™ Tibial Drill Guide	-
 Downsize Plan Upsize	42-411430	Signature™ Femoral Drill Guide	X-small
	42-411431	Signature™ Femoral Drill Guide (Upsize)*	Small
	42-411434	Signature™ Femoral Drill Guide (Downsize)*	X-small
	42-411435	Signature™ Femoral Drill Guide	Small
	42-411436	Signature™ Femoral Drill Guide (Upsize)*	Medium
	42-411439	Signature™ Femoral Drill Guide (Downsize)*	Small
	42-411440	Signature™ Femoral Drill Guide	Medium
	42-411441	Signature™ Femoral Drill Guide (Upsize)*	Large
	42-411444	Signature™ Femoral Drill Guide (Downsize)*	Medium
	42-411445	Signature™ Femoral Drill Guide	Large
	42-411446	Signature™ Femoral Drill Guide (Upsize)*	X-large
	42-411449	Signature™ Femoral Drill Guide (Downsize)*	Large
	42-411450	Signature™ Femoral Drill Guide	X-large

*Optional to be used for intraoperative sizing if altering from approved Signature™ plan.

*A collaborative partnership with Materialise N.V.

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Form No. BOI0495.0 • REV073111