Oxford® Fixed Lateral Partial Knee

Surgical Technique

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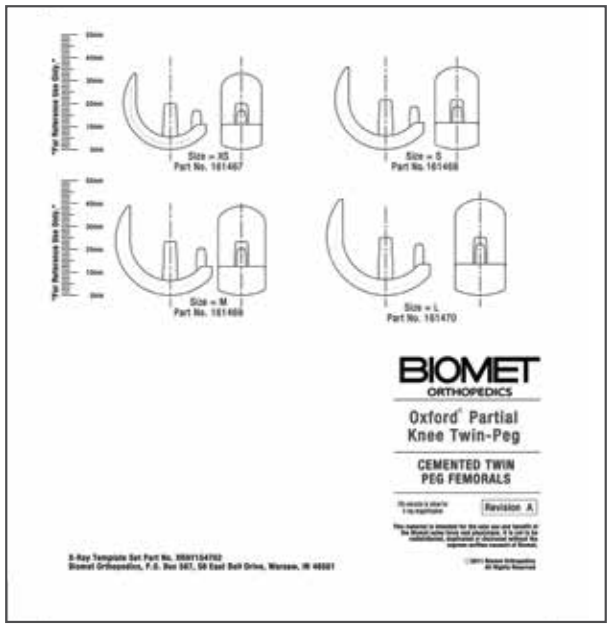


Figure 1

Preoperative Planning

Choose the femoral component size preoperatively using the X-ray template (Figure 1). Apply the template outlines to the X-ray image of the appropriate condyle. A lateral radiograph is required for a lateral compartment operation. The line along the central peg of the implant should be slightly flexed relative to the long axis of the femoral shaft. The outer surface of the diagrammatic component should lie about 2 mm outside the radiographic image to allow for articular cartilage thickness. The posterior facet of the prosthesis should extend to, but not beyond, the superior margin of the posterior articular facet of the femur.

1. Hall et al. Unicompartmental Knee Arthroplasty (Alias Uni-Knee)-An Overview with Nursing Implications. Orthopedic Nursing. 2004;23(3):163-171.
2. Brown, NM, et al. Total Knee Arthroplasty Has Higher Postoperative Morbidity Than Unicompartmental Knee Arthoplasty: A Multicenter analysis. The Journal of Arthroplasty. 2012. Published Online.
3. Deshmukh, RV, Scott, RD. "Unicomparmental knee arthroplasty: long-term results." Clinical Orthopedics and Related Research. 2001; 392:272-278.

Open vs. Minimally Invasive Technique

One advantage of partial knee arthroplasty is that it can be performed through a small incision without dislocating the patella, thus avoiding damage to the synovial reflections of the suprapatellar pouch. With proper use of the Oxford Microplasty® instrumentation, the Oxford Fixed Lateral operation can be performed through a small incision. Surgeons learning the procedure, however, can extend the soft tissue incision beyond the limits described here with very little increase in postoperative morbidity, as long as the integrity of the suprapatellar pouch is respected.

The open approach, with dislocation of the patella, is not recommended. The instrumentation is designed for use through a small incision, and intraoperative dislocation of the patella distorts the ligaments which may make the operation more difficult to perform.

Figure 2

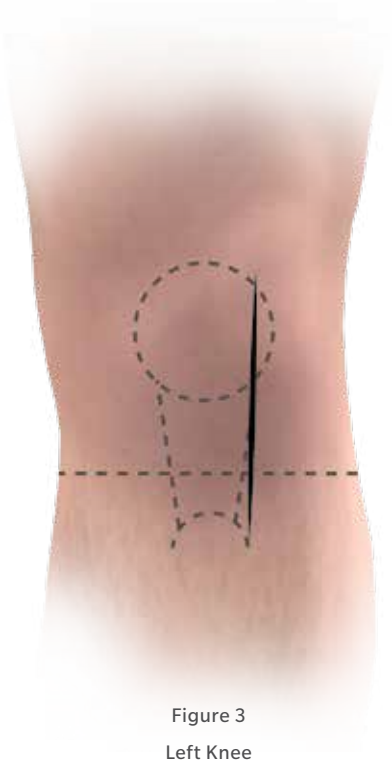


Figure 3
Left Knee

Positioning the Limb

Attach 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 (Figure 2). The thigh support must not be placed in the popliteal fossa as this will increase the risk of damage to the popliteal vessels.

Incision

Start the incision at the top of the patella, over the junction mid and lateral 1/3 of patella. End the incision lateral to the tibial tubercle. The retinacular incision is made around patella and extended proximally within quads tendon.

Inspection

The joint is examined to assess the state of the following:

- The anterior cruciate ligament must be functionally intact
- The patello femoral joint is assessed
- The medial compartment is examined. Full thickness cartilage lesion on the medial femoral condyle is considered a contraindication for a lateral PKA. It may be difficult to view the medial side of the joint. If there is a concern about potential arthritis in the medial compartment, an arthroscopy may need to be performed to assess the joint.

If exposure is difficult, 5 mm of bone can be removed from the lateral side of the patella.

Lateral Compartment Replacement

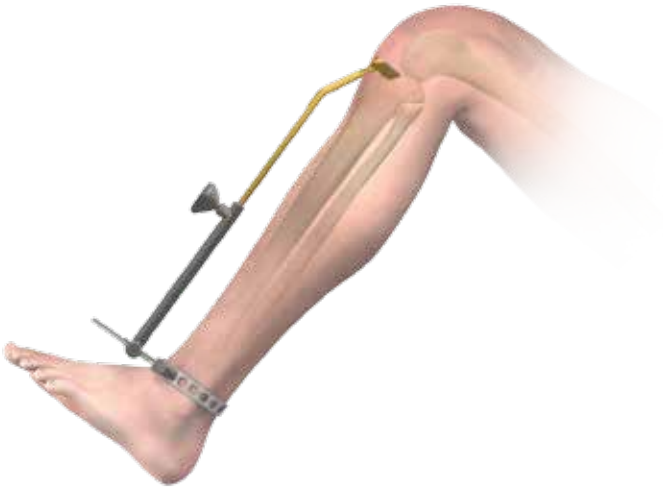


Figure 4

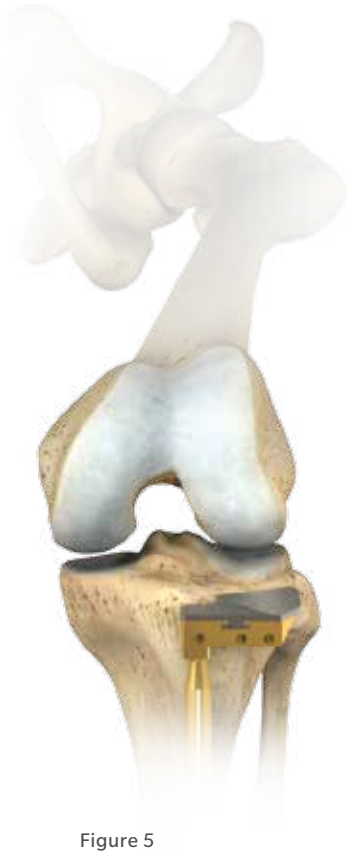


Figure 5

Tibial Plateau Resection

Expose the front of the tibia in the lower part of the wound from the tibial tubercle to the rim of the plateau and Gerdy's tubercle. Excise as much of the lateral meniscus as possible.

The track of articulation on the lateral femoral condyle is internally rotated. Therefore, the component must be internally rotated to allow for accurate femoral articulation. With the appropriate 0 mm uncaptured shim assembled use the right medial resection guide for the left lateral tibial plateau and vice versa. Ensure the tibial resection guide is parallel with the spine of the tibia. This will allow 7 degrees of posterior slope (Figure 4).

Manipulate the upper end of the guide so that its face lies against the exposed bone. A recess accommodates the skin and the patellar tendon medially (Figure 5). The lateral tibial resection should be 1 to 2 mm below the deepest part of the erosion, unless it is very deep, in which case the cut should be above the bottom of the defect.

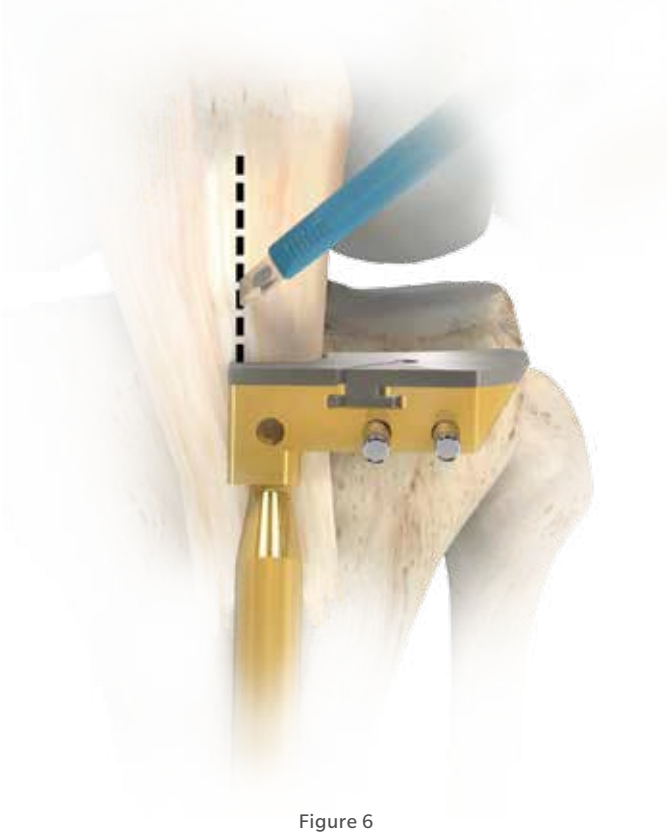


Figure 6

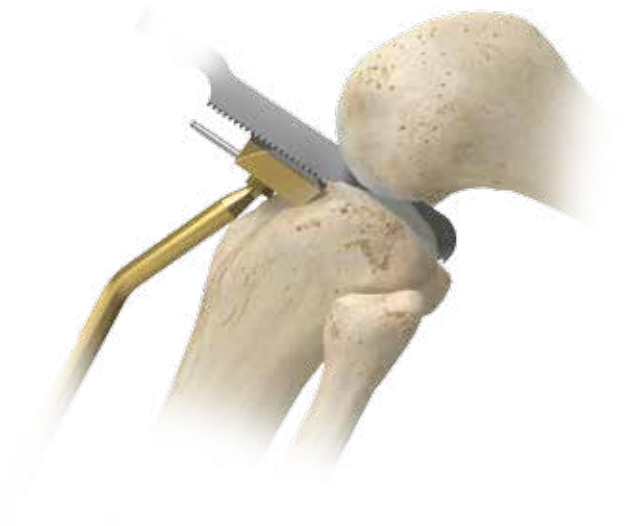


Figure 7

Tibial Plateau Resection (cont.)

When pinning the guide, the middle pin hole may be used to secure the guide utilizing a drill pin.
The presence of the patellar tendon may cause external rotation of the vertical cut.

With the Oxford Leg holder

Expose the anterior surface of the patellar tendon. Make a vertical splice into the mid-patellar tendon (Figure 6). Insert a stiff sagittal saw through the patellar tendon above the tibial plateau. Point the blade toward the anterior superior iliac spine or in the flexion plane of the knee. This allows correct internal rotation of the tibial component in cases where the patellar tendon is tight and visualization is difficult.

Without the Oxford Leg holder

The patellar tendon should not be in the way when the leg is positioned on the table. Therefore there is no need to splice the patellar tendon. The vertical cut should be aimed at the anterior superior iliac spine, or in the flexion plane of the knee.

The saw must reach the back of the tibial plateau and a little beyond. This is achieved by lining up the appropriate mark on the saw with the anterior cortex. Advance the saw vertically down until it rests on the surface of the saw guide (Figure 7). The saw must remain parallel to the guide. Do not lift the saw handle as this will dip the saw blade and increase the risk of tibial plateau fracture.

Lateral Compartment Replacement

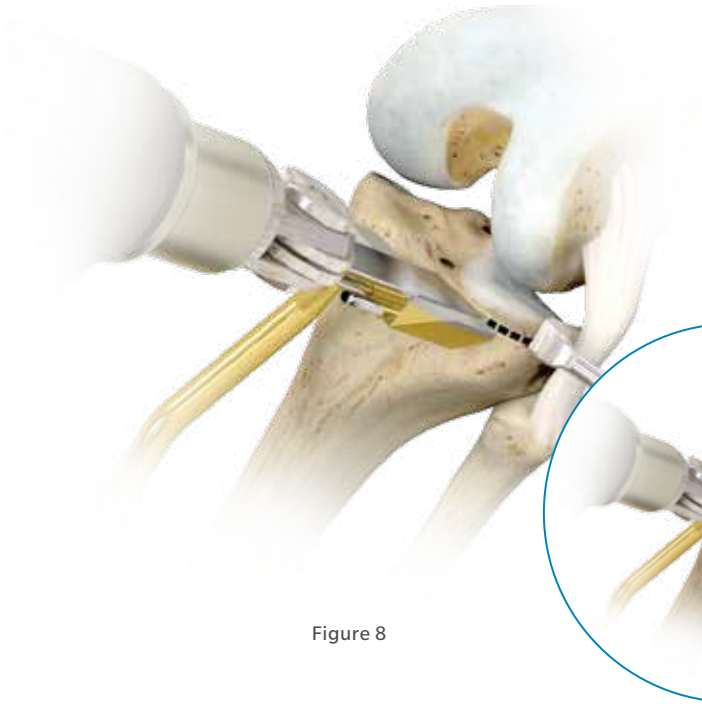


Figure 8

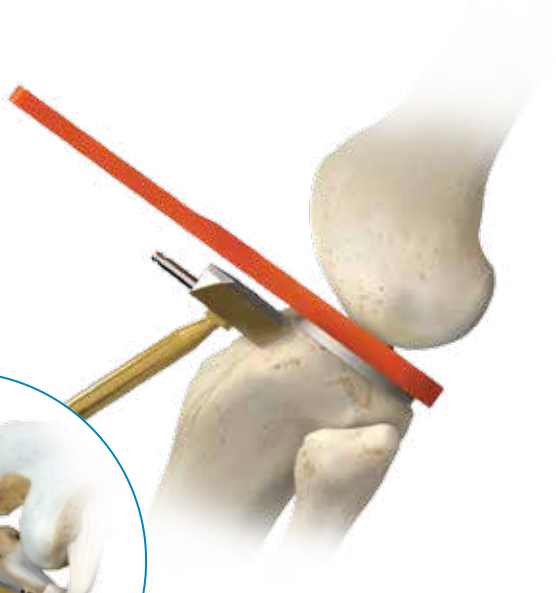


Figure 9

Tibial Plateau Resection (cont.)

The collateral ligament retractor (curly whirly) should be inserted so that the horizontal saw cut does not damage the soft tissues laterally, in particular the iliotibial tract and the posteriorly positioned lateral collateral ligament.

Use a 12 mm wide oscillating saw blade with appropriate markings to excise the plateau (Figure 8). Ensure the saw blade is guided along the curly whirly to completely cut the lateral cortex. To cut the posterior cortex, deepen the cut until the appropriate mark on the saw blade is aligned with the anterior cortex. When the plateau is loose, lever it up with a broad osteotome and remove. The tibial plateau is usually removed with ease and is then sized to the opposite template.

Note: When making the horizontal cut a slotted shim may be used. This can be done by replacing the initial uncaptured 0 mm shim with the corresponding slotted shim. The slotted shim helps maintain the 7 degree posterior slope during the resection (Figure 8 inset).

To confirm that enough bone has been resected from the tibia, the tibial template should be inserted and the knee fully extended. If a size 4 feeler gauge (or size 3 in small women) cannot be inserted in full extension (Figure 9) the tibia should be recut. To do this, remove the initial 0 mm shim from the guide (Figure 9), using the small nub on the Oxford IM Rod Removal Hook. Once the shim is removed, extend the reciprocating resection and using the oscillating saw resect off the surface of the guide to remove 2 mm additional bone. After the additional resection, recheck the gap with the feeler gauge. The flexion gap should be checked, and should be loose.

Note: Whenever assessing tension to measure a gap, remove the retractors. If left in, they will tighten the soft tissues, which artificially diminishes the gap.

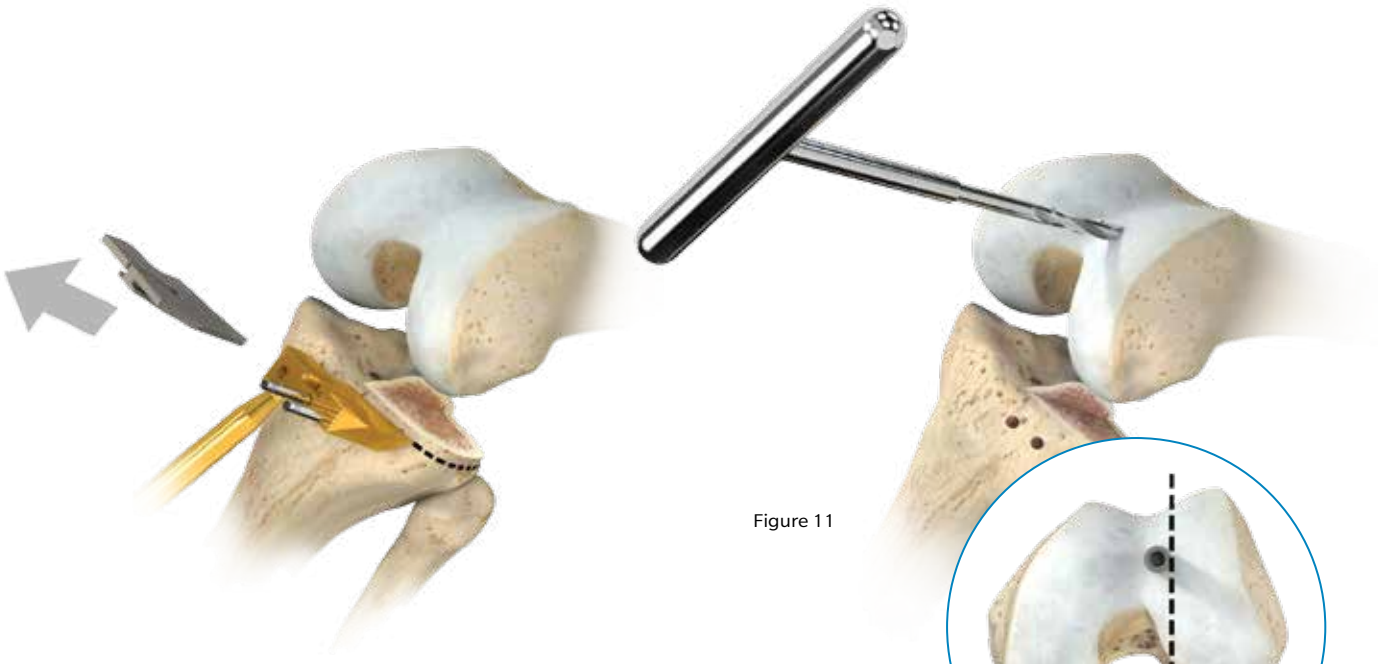


Figure 10

Figure 11

Figure 12

Femoral Preparation

The Oxford Fixed Lateral Partial Knee offers both intramedullary (IM) and extramedullary (EM) alignment options. Both options are covered in the following sections.

Using methylene blue or diathermy, draw a line down the center of the lateral condyle.

Positioning the Femoral Drill Guide: IM Option

With the knee in about 45 degrees of flexion, make a hole in the intramedullary canal of the femur with the 4 mm drill followed by the 5 mm awl (Figure 11). The hole must be situated 1 cm anterior to the anterior edge and just lateral to the lateral wall of the intercondylar notch (Figure 12). It should aim for the anterior superior iliac spine.

Lateral Compartment Replacement

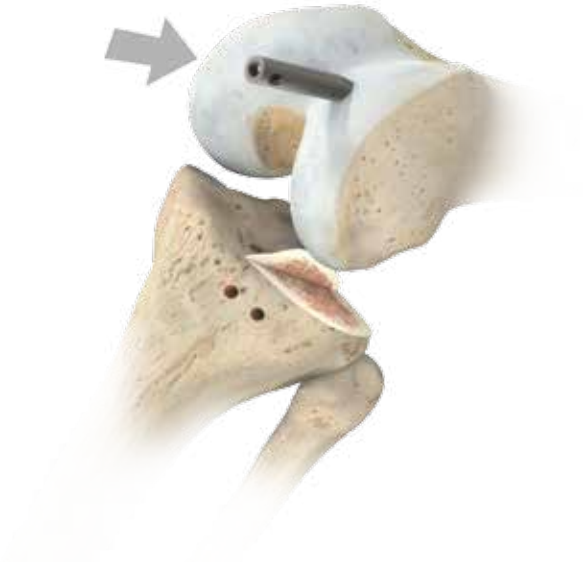


Figure 13

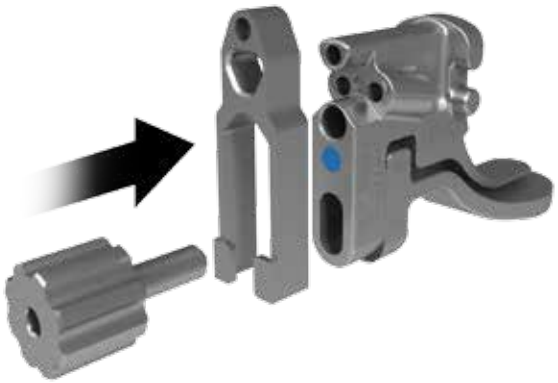


Figure 14

Positioning the Femoral Drill Guide: IM Option (cont.)

Using the IM rod pusher, insert the intramedullary rod until the pusher shoulder stops against the bone (Figure 13).

Flex the knee to 90 degrees. This must be done with care, as the lateral border of the patella abuts the IM rod.

The IM adaptor must be assembled onto the Microplasty femoral drill guide. To assemble, remove the thumb screw from the drill guide, place the IM adaptor on the drill guide with the holes as shown in Figure 14. Screw the thumb screw over the IM adaptor.

With the knee flexed to 90 degrees, insert the Microplasty femoral drill guide adjusted to ensure that the foot of the drill guide is in contact with the posterior femoral condyle.

Figure 15

Positioning the Femoral Drill Guide: IM Option (cont.)

The Microplasty femoral drill guide must be placed up against the distal lateral femoral condyle. Insert the IM link into the IM rod and into the anterior hole of the IM adaptor. This will flex the femoral component 5 degrees (Figure 15).

When viewed from a distal view, manipulate the femoral drill guide until it is in the middle of the condyle, in line with the methylene blue or diathermy drawn down the center of the lateral condyle. The foot of the femoral drill guide should be touching the posterior femoral condyle.

Advance the 4 mm drill through the anterior hole of the femoral drill guide until it stops. Leave the 4 mm drill in the drill guide. Advance the 6 mm drill through the posterior hole in the guide until it stops.

Remove the 4 mm and 6 mm drills, and the femoral drill guide.

Note: The link piece of the IM Link may need to be positioned upwards in order for the 4 mm drill to fully seat in the 4 mm drill hole in the femoral drill guide.

Lateral Compartment Replacement

Figure 16

Figure 17

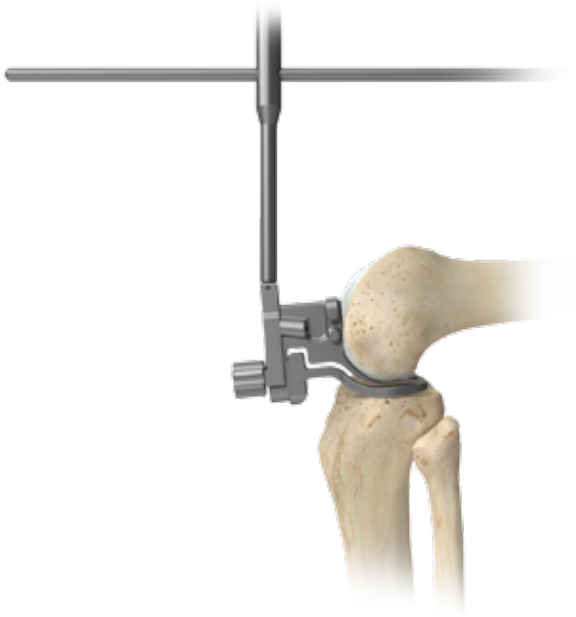


Figure 18

Femoral Preparation (cont.)

Positioning the Femoral Drill Guide: EM Option

To attach the EM adaptor to the Microplasty femoral drill guide, remove the thumb screw from the drill guide, and place the EM adaptor on the face of the drill guide, with the alignment rod holder facing upward (Figure 16). Screw the thumb screw over the EM adaptor.

Flex the knee to 90 degrees and insert the Microplasty femoral drill guide, ensuring that the foot of the drill guide is in contact with the posterior femur.

When viewed from a distal view, manipulate the femoral drill guide until it is in the middle of the condyle, in line with the methylene blue or diathermy drawn down the center of the lateral condyle. Insert the alignment rod into either hole in handle of the EM adaptor.

When viewed from a sunrise view, align the drill guide to be parallel with the femur (Figure 17).

When viewed laterally, align the EM alignment rod parallel with the natural femur. The holes and shaft of the EM adaptor, with the EM rod parallel to the femur, will flex the femoral component 5 degrees (Figure 18).

Advance the 4 mm drill through the anterior hole of the femoral drill guide until it stops. Leave the 4 mm drill in the drill guide. Advance the 6 mm drill through the posterior hole in the guide until it stops.

Remove the 4 mm and 6 mm drills, and the femoral drill guide.

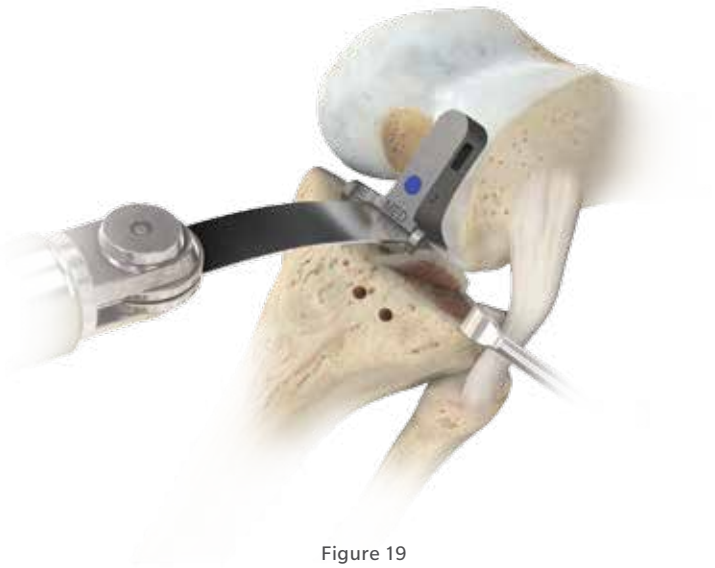


Figure 19

Femoral Saw Cut

Insert the Microplasty posterior resection guide into the drilled holes in the distal femur.

Insert a retractor to protect the LCL. 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 19). Take care to avoid damage to the lateral collateral ligament.

Remove the guide with the slap hammer, ensuring that it is withdrawn in line with the femoral drill holes as to not damage them. Remove the posterior fragment.

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

Special Note

Before advancing to the following surgical steps, consult the special note below.

The thickness of the tibial components increase with increments of 1 mm.

The scale of numbers of the spigots is in 1 mm increments, in inverse ratio to the thickness of their flanges.

The spigots must be used as described below:

- **First Milling**
  The 0 spigot is designed to automatically remove sufficient bone to allow the femoral component to seat. This amount varies with the degree of arthritic erosion of the condyle.
- **Second Milling**
  Spigots 1 to 7 allow bone to be removed in measured quantities (mm) from the level of the first mill cut. Thus, the number 3 spigot removes 3 mm, the number 4, 4 mm, etc.
- **Subsequent Milling**
  If the last spigot used was a number 3, a number 4 spigot will remove an additional 1 mm of bone (i.e. a total of 4 mm since the first milling). However, if the last spigot used was a number 4, a number 5 spigot is required to remove 1 mm of bone (i.e. a total thickness of 5 mm since the first milling).

Remember:
The spigot number represents the total thickness of bone it removes from the level of the first mill cut.

Important:
We recommend against using the 5 spigot or higher in the lateral compartment, as this will elevate the joint line.

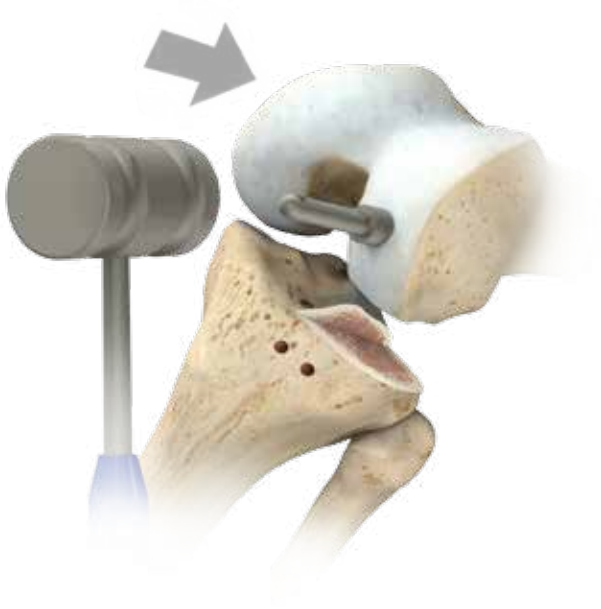


Figure 20

First Milling of the Condyle

Insert the 0 spigot, which has the thickest flange, into the 6 mm large drill hole and tap it home until the flange abuts the bone (Figure 20). The 0 spigot is the only spigot that may be tapped into place, all other spigots should be placed and seated by finger pressure.

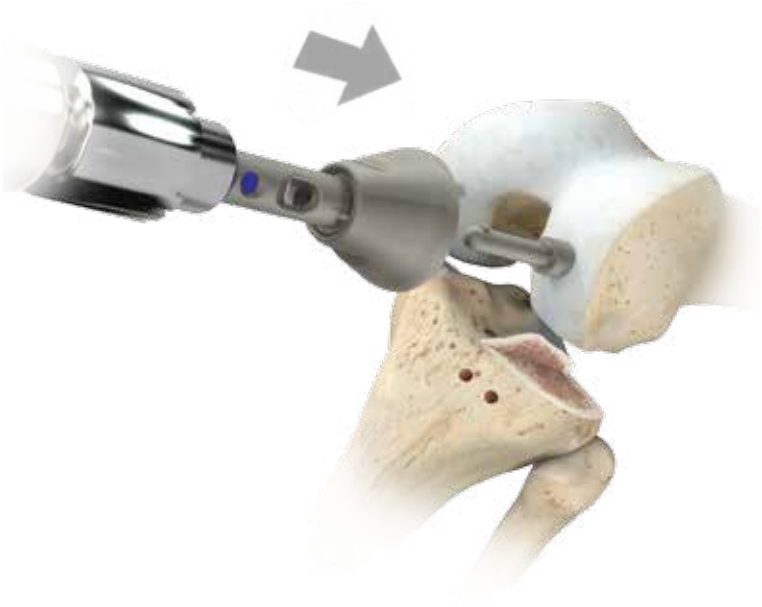


Figure 21

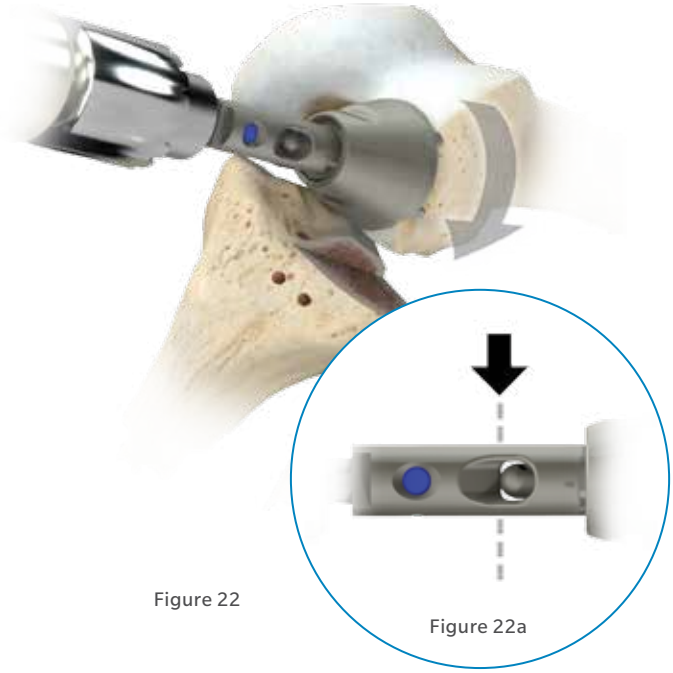


Figure 22

Figure 22a

First Milling of the Condyle (cont.)

By slightly extending the knee and retracting the soft tissues, maneuver the low profile spherical cutter of corresponding size and color onto the spigot and into the wound so that its teeth touch the bone (Figure 21).

Take care to avoid trapping soft tissues prior to starting the mill.

When milling, push firmly in the direction of the spigot axis, taking care not to tilt the mill (Figure 22). Mill until the cutter will no longer advance and the spigot can be seen, in the window, to have reached its end stop (Figure 22a).

Figure 23

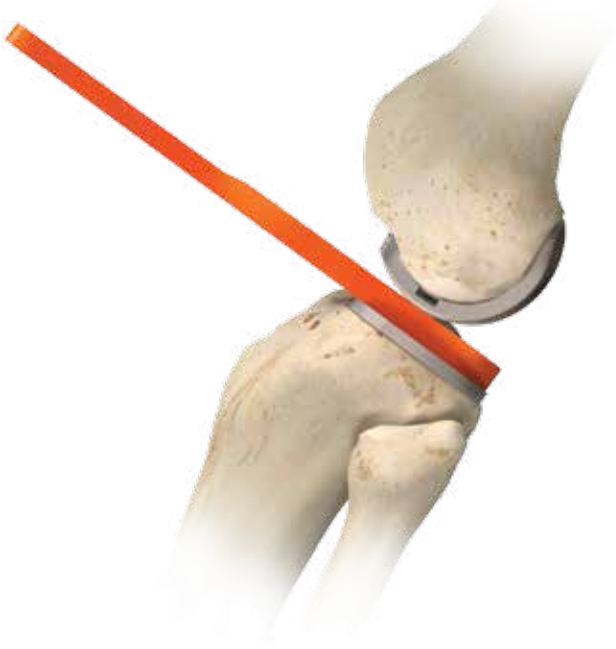


Figure 24

First Milling of the Condyle (cont.)

Remove the mill and spigot and trim off the bone protruding from the posterior corners of the condyle that lie outside the periphery of the cutting teeth (Figure 23). These corners should be removed tangentially to the milled surface, taking care not to damage the flat posterior surface of the condyle.

Determining the Amount of Extension Gap to be Milled

Insert the tibial template and femoral trial of corresponding size to the milled condyle, tapping it home with the femoral impactor angled at 45 degrees to the femoral axis.

Step A: Measure Extension Gap

The extension gap is measured in full extension, when the LCL is tight, thus enabling restoration of leg alignment to the predisease situation (Figure 24). If measured in 20 degrees of flexion, as done in medial partial knees, the LCL is loose and gives a false measurement.

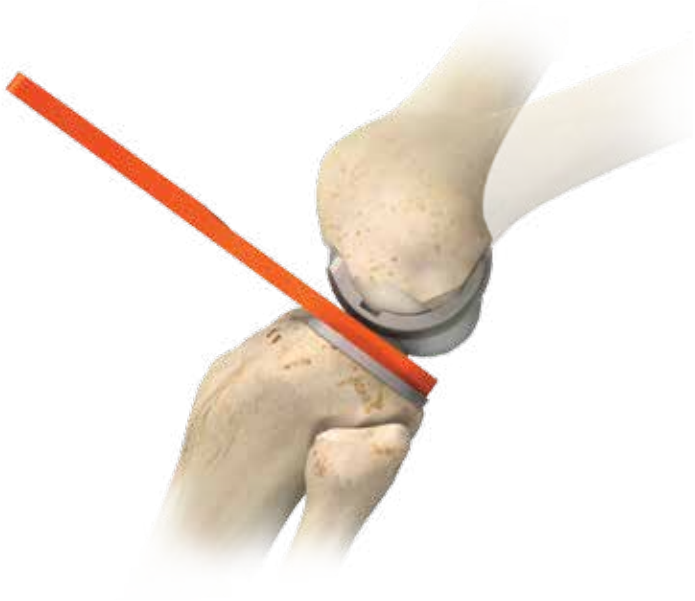


Figure 25

Determining the Amount of Extension Gap to be Milled (cont.)

Step B: Ensuring the Flexion Gap is Lax

With the knee in 95 degrees of flexion, insert a feeler gauge 2 mm thicker than the measured extension gap. This will determine that the flexion gap is at least 2 mm larger than the extension gap (Figure 25).

Step C: Determine the Second Milling

The goal of the second milling is to achieve the size that was initially measured after the tibial resection. If a size 4 was initially measured in extension, and a 2 feeler gauge can be inserted in extension after the first milling, then a 2 spigot should be utilized.

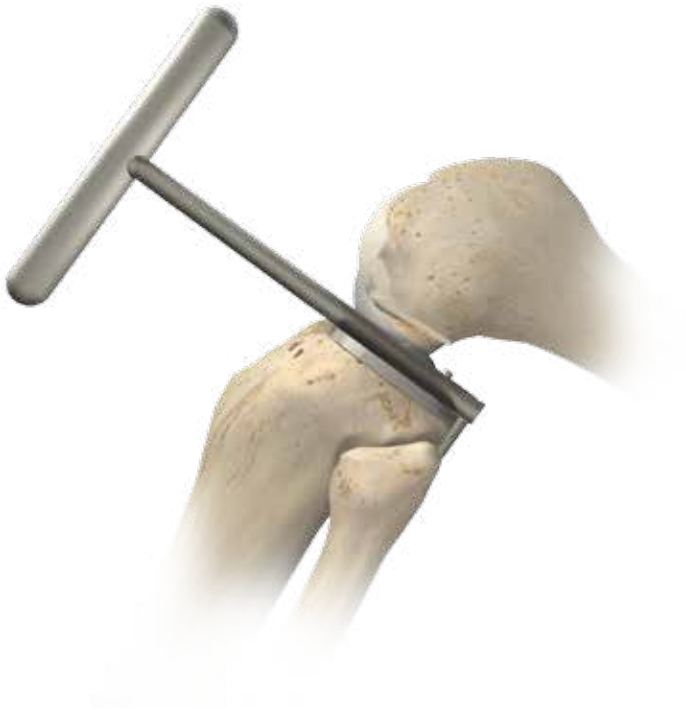


Figure 26

Confirming of the Flexion and Extension Gaps

With the tibial template and the femoral trial component in place, re-measure the flexion and extension gap. The flexion gap should be more lax than the extension gap (in full extension).

If the targeted size feeler gauge still cannot be inserted in extension, remove additional bone with the mill. This is done by following the steps described in step C of the previous section.

Additional bone can be removed at 1 mm increments, by using the sequence of spigots. A spigot 5 or higher should never be used in the lateral compartment as this will elevate the tibial joint line.

The final implant is chosen in extension.

Final Preparation of the Tibial Plateau

Insert the chosen size tibial template and position its posterior margin flush with the posterior tibial cortex. Facilitate this by passing a small hook over the posterior margin of the tibia (Figure 26). A final assessment of the tibial size should be made. An ideally sized component should be flush with the bone in the region of Gerdy's tubercle and should not overhang in this region.

The keel slot is prepared (placing the leg in a figure-of-four position will allow better access to the tibial plateau).

Once properly placed, the long bone nail should be utilized to secure the placement.

Figure 27

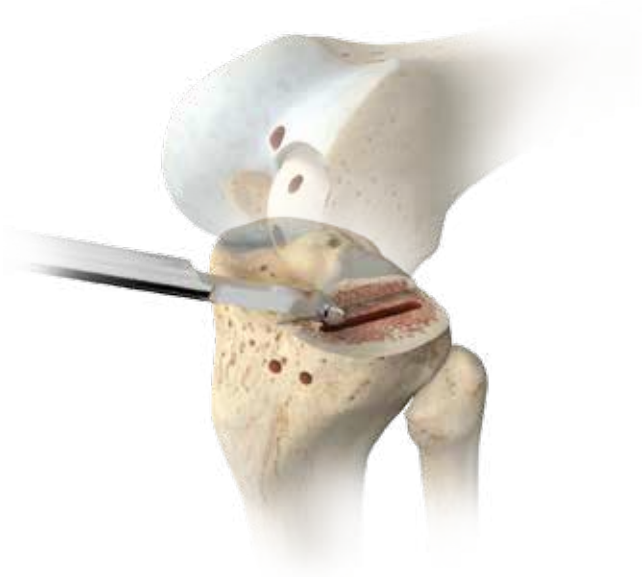


Figure 28

Keel Resection

When preparing the 10 mm deep slot for the tibial keel, the cemented toothbrush sawblade must be utilized through the tibial template (Figure 27).

After removing the tibial template, excavate the groove to the correct depth by scooping out the bone with the blade of the tibial pick, taking care not to damage the anterior and posterior cortices (Figure 28).

The safest way to prepare the back of the groove is to feel the posterior cortex with the tibial keel pick and then move it anteriorly by 5 mm before pushing down and bringing forward to empty the groove.

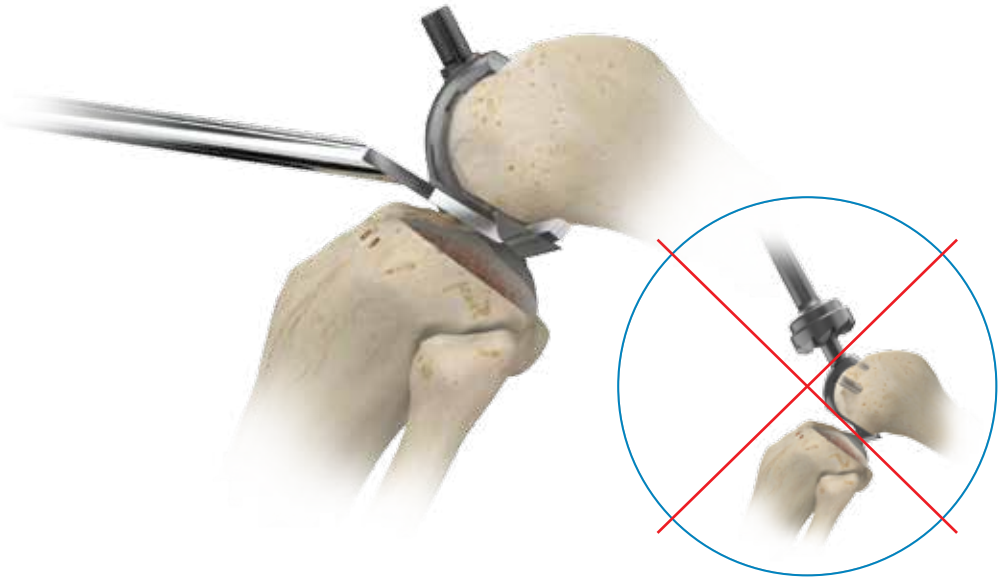


Figure 29

DO NOT USE THE ANTERIOR MILL

Keel Resection (cont.)

Insert the tibial trial component and tap home with the tibial impactor until fully seated. It is easiest to insert the tibial trial when the leg is held in a figure-of-four position.

Ensure the component is flush with the bone and the posterior margin extends to the back of the tibia. If the component does not seat fully remove it and clean the keel slot out again with the tibial pick.

Use only the toffee hammer to avoid the risk of plateau fracture.

Remove the tibial trial component once confirmed that it sits flush to the bone.

Reducing Impingement

Note: Do not use the anterior mill as this removes too much bone anteriorly and increases the risk of the patella jamming into the milled area.

Final preparation of the femur requires trimming of the condyle posteriorly to reduce the risk of impingement of bone against the polyethylene bearing surface in full flexion. Apply the anti-impingement guide to the condyle and use the posterior osteophyte chisel to remove any posterior osteophytes (Figure 29).

Remove the anti-impingement guide. If needed, anterior cartilage can be removed with a nibbler, or small chisel, until there is at least 1 mm of clearance between the bone and the polyethylene in full extension.

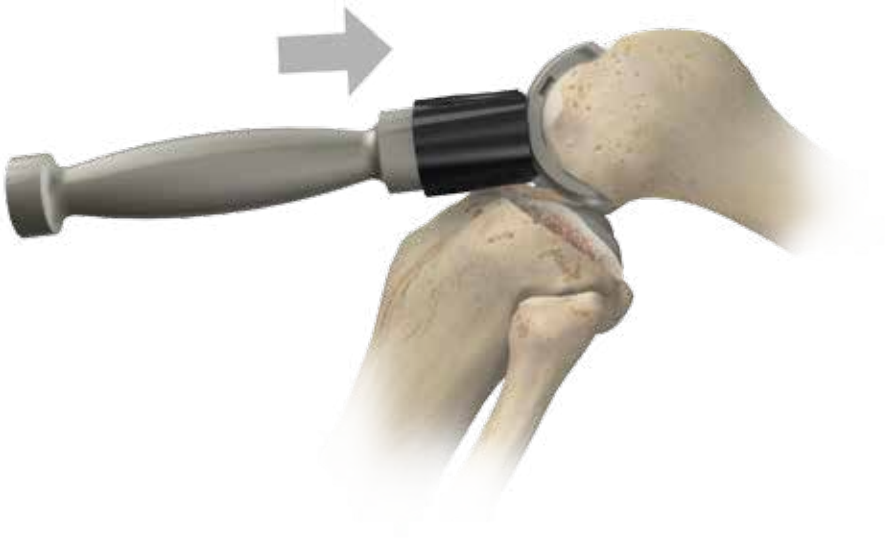


Figure 30

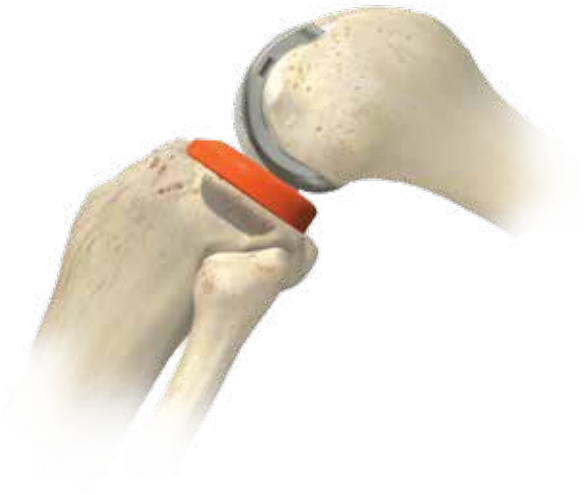


Figure 31

Final Trial Reduction

Insert the femoral trial component and fully seat it using the femoral impactor at 45 degrees to the femoral axis (Figure 30).

With the knee now ready for final trialing, it is time to select the appropriate tibial trial. This is done by choosing the size of the tibial template that was used to prepare the keel slot (A, B, C, D, E, or F), as well as the size that corresponds with the extension gap (3, 4,5, 6, or 7).

For example, if the C tibial template was used to prepare the keel slot, and the extension gap measured size 5, the C5 tibial trial is chosen.

Insert the chosen tibial trial, and manipulate the knee through a full range of motion to demonstrate stability of the joint and absence of impingement (Figure 31). It is easiest to insert the tibial trial when the leg is held in a figure-of-four position.

The thickness of the tibial component should restore the ligaments to their natural tension. When a varus force is applied to the knee, the artificial joint surfaces should distract 1–2 mm. Complete this test with the knee in full extension.

Note: Take care not to overcorrect the knee into varus or damage the LCL by inserting too thick of a tibial component.

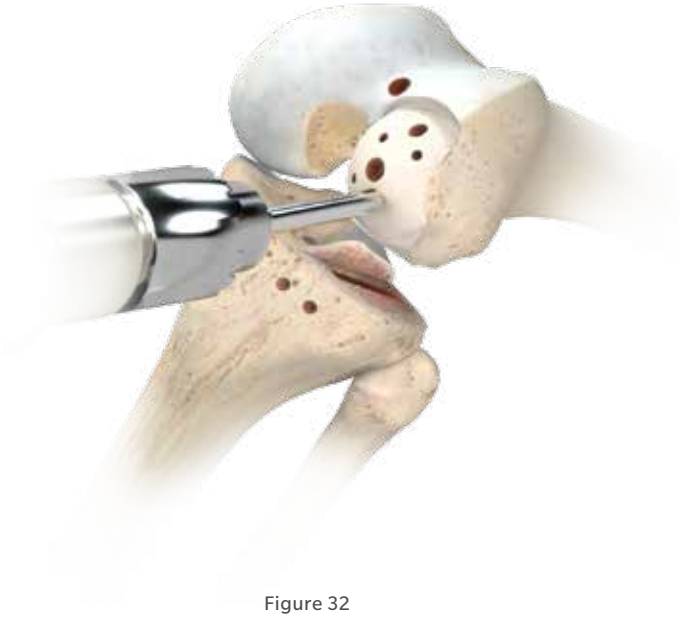


Figure 32

Cementing the Components

When using the leg holder, the femur is cemented first, then the tibia.

When not using the leg holder, the tibia should be cemented first, and then the femur.

Roughen the femoral and tibial surfaces, including the posterior condyles, by making multiple small drill holes with the cement key drill (Figure 32).

Femoral Component

Force cement into the large femoral drill hole and fill the concave surface of the femoral component with cement. Apply the loaded component to the condyle and impact with the impactor held at 45 degrees to the long axis of the femur. Remove excess cement from the margins with a Woodson cement curette.

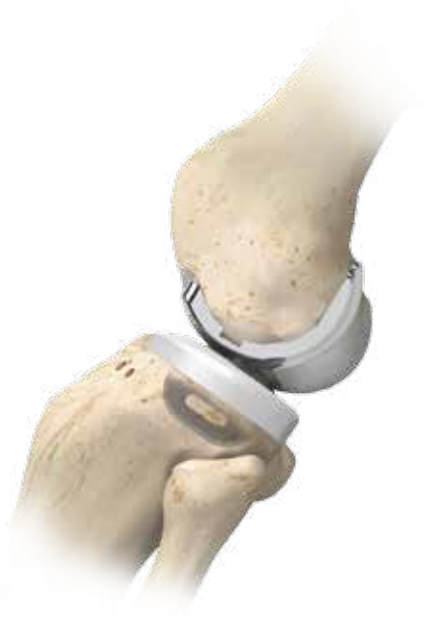


Figure 33

Cementing the Components (cont.)

Tibial Component

Place a small amount of cement on the tibial bone surface and flatten to produce a thin layer covering the whole under surface. Place the cement on the under surface of the tibial implant. Insert the component and press down, first posteriorly and then anteriorly, so that excess cement is squeezed out at the front. It is easiest to insert the tibial component when the leg is held in the figure four position.

Use the microscope tibial impactor (with the toffee hammer) to complete the insertion. Ensure there is no soft tissue under the component. Remove excess cement with a Woodson small curette from the margins of the component.

Pressurize the cement by inserting the appropriate plastic 2 mm feeler gauge from the Microplasty set with the knee at 45 degrees of flexion and holding the leg in this position. Do not extend or flex the knee or this may rock the components and may loosen them.

Once the cement has set, remove the feeler gauge. Clear the medial and lateral margins of the component of any extruded cement. The posterior margin cannot be seen but can be palpated with a curved dissector. Close the wound in routine fashion.

Sizing Overview

Component Sizing - Construct Thickness

Size	Construct		Total Construct
	Tibial Base Plate	Polyethylene	
3	3 mm	5 mm	8 mm
4	3 mm	6 mm	9 mm
5	3 mm	7 mm	10 mm
6	3 mm	8 mm	11 mm
7	3 mm	9 mm	12 mm

Table 1

Feeler Gauge Sizing - Thickness

Nomenclature	Thickness
1	3 mm
2	4 mm
Size 3	5 mm
Size 4	6 mm
Size 5	7 mm
Size 6	8 mm
Size 7	9 mm

Table 2

The feeler gauges are equal to the polyethylene thickness of the corresponding size.

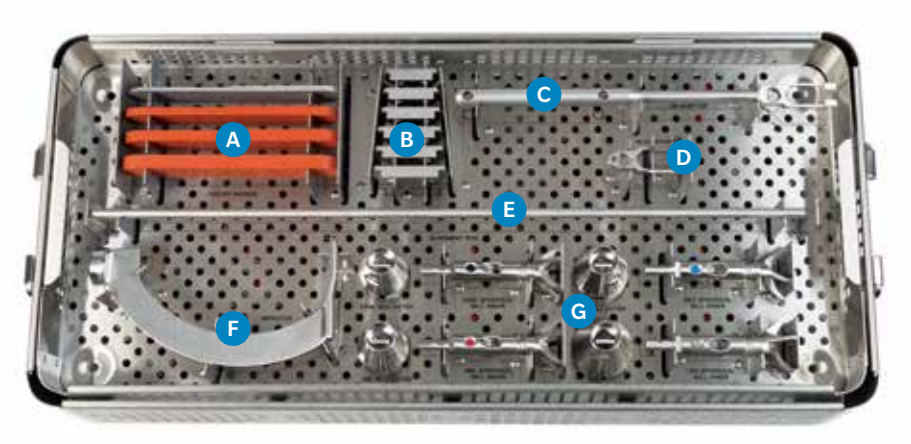
Implant and Instrument Overview

Product	Description	Size	Part Number
	**Oxford Twin Peg Femoral Component**	**X-small**	161467
		Small	161468
		Medium	161469
		Large	161470

Oxford Fixed Lateral Tibial Component

Product	Left Lateral	Size	Right Lateral	Size
	154320	**A3**	154350	**A3**
	154321	**A4**	154351	**A4**
	154322	**A5**	154352	**A5**
	154323	**A6**	154353	**A6**
	154324	**A7**	154354	**A7**
	154325	**B3**	154355	**B3**
	154326	**B4**	154356	**B4**
	154327	**B5**	154357	**B5**
	154328	**B6**	154358	**B6**
	154329	**B7**	154359	**B7**
	154330	**C3**	154360	**C3**
	154331	**C4**	154361	**C4**
	154332	**C5**	154362	**C5**
	154333	**C6**	154363	**C6**
	154334	**C7**	154364	**C7**
	154335	**D3**	154365	**D3**
	154336	**D4**	154366	**D4**
	154337	**D5**	154367	**D5**
	154338	**D6**	154368	**D6**
	154339	**D7**	154369	**D7**
	154340	**E3**	154370	**E3**
	154341	**E4**	154371	**E4**
	154342	**E5**	154372	**E5**
	154343	**E6**	154373	**E6**
	154344	**E7**	154374	**E7**
	154345	**F3**	154375	**F3**
	154346	**F4**	154376	**F4**
	154347	**F5**	154377	**F5**
	154348	**F6**	154378	**F6**
	154349	**F7**	154379	**F7**

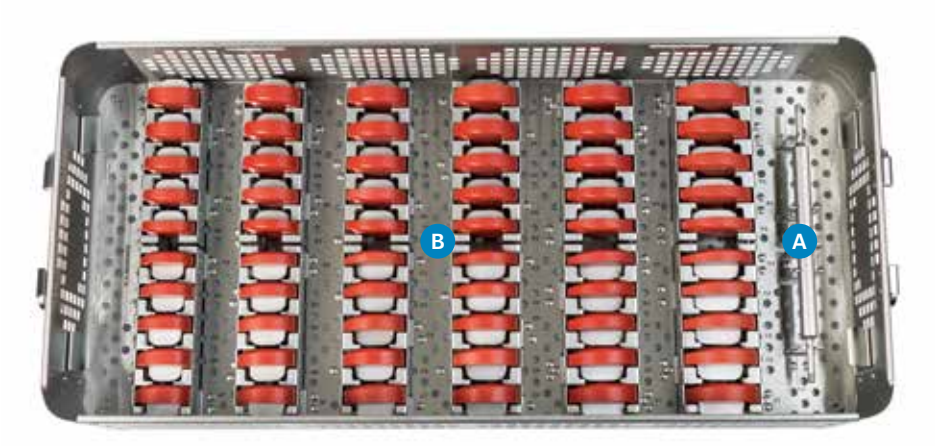
Instrument Tray



Oxford Fixed Lateral Case - 32-423392 (EMPTY: 32-423394) - Upper Insert Tray

Product	Description	Label	Size	Part Number
	**Oxford Fixed Lateral Gap Gauge**	**A**	**1/2** **3/4** **5/6** **7**	32-423346 32-423347 32-423348 32-423349
	**Oxford Fixed Lateral Tibial Template**	B	**A** **B** **C** **D** **E** **F**	32-423331 32-423332 32-423333 32-423334 32-423335 32-423336
	**Oxford Fixed Lateral EM Adaptor**	**C**	-	32-423300
	**Oxford Fixed Lateral IM Adaptor**	**D**	-	32-423400
	**EM Alignment Rod**	**E**	-	32-466616
	**Tibial Impactor**	**F**	-	US32-421041
	**Low Profile Spherical Mill**	**G**	**X-small** **Small** **Medium** **Large**	32-423350 32-423351 32-423352 32-423353

Instrument Tray



Oxford Fixed Lateral Case - 32-423392 (EMPTY: 32-423394) - Lower Insert Tray

Product	Description	Label	Size	Part Number
	**Oxford Fixed Lateral Trial Bearing Handle**	**A**	**-**	32-423354

Oxford Fixed Lateral Trial Bearing

Product	Label	Left Lateral	Size	Right Lateral	Size
	**B**	32-423001	**A3**	32-423362	**A3**
		32-423002	**A4**	32-423363	**A4**
		32-423003	**A5**	32-423364	**A5**
		32-423004	**A6**	32-423365	**A6**
		32-423005	**A7**	32-423366	**A7**
		32-423006	**B3**	32-423367	**B3**
		32-423007	**B4**	32-423368	**B4**
		32-423008	**B5**	32-423369	**B5**
		32-423009	**B6**	32-423370	**B6**
		32-423010	**B7**	32-423371	**B7**
		32-423011	**C3**	32-423372	**C3**
		32-423012	**C4**	32-423373	**C4**
		32-423013	**C5**	32-423374	**C5**
		32-423014	**C6**	32-423375	**C6**
		32-423015	**C7**	32-423376	**C7**
		32-423016	**D3**	32-423377	**D3**
		32-423017	**D4**	32-423378	**D4**
		32-423018	**D5**	32-423379	**D5**
		32-423019	**D6**	32-423380	**D6**
		32-423020	**D7**	32-423381	**D7**
		32-423021	**E3**	32-423382	**E3**
		32-423022	**E4**	32-423383	**E4**
		32-423023	**E5**	32-423384	**E5**
		32-423024	**E6**	32-423385	**E6**
		32-423025	**E7**	32-423386	**E7**
		32-423026	**F3**	32-423387	**F3**
		32-423027	**F4**	32-423388	**F4**
		32-423028	**F5**	32-423389	**F5**
		32-423029	**F6**	32-423390	**F6**
		32-423030	**F7**	32-423391	**F7**

UK

Oxford Partial Knee System - Femoral, Fixed Bearing Tibial and Domed Lateral Tibial Trays and Bearing Components

Attention Operating Surgeon

DESCRIPTION
The Oxford Fixed Bearing Knee is a Partial knee replacement system consisting of a femoral component and a fixed bearing tibial component intended for use in the lateral compartment of the knee.

Furthermore, this packaging insert is intended for all cemented femoral components within the Oxford Partial Knee system and Oxford Domed Lateral tibial trays and bearings. **The components of the Oxford Domed Lateral are not approved for sale in the United States.**

Materials

Femoral component	CoCrMo Alloy
Fixed Lateral Tibial component	CoCrMo Alloy/ ArCom Ultra-High Molecular Weight Polyethylene (UHMWPE)
Domed lateral mobile Bearings	Ultra-high-molecular weight polyethylene, titanium marker wires
Domed Lateral Tibial Tray	CoCrMo Alloy

INDICATIONS
Partial replacement of the articulating surfaces of the knee when only one side of the knee joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous partial arthroplasty in the affected compartment.

The Oxford Fixed Lateral bearings are indicated for use in the lateral compartment and intended to be implanted with bone cement.

The Oxford Fixed Lateral components are indicated for use in the lateral compartment for a fixed bearing application. They are intended to be implanted with bone cement.

The Oxford Femoral components are also indicated for use in the medial compartment for a mobile bearing application. For mobile bearing articulation in the medial compartment with the Oxford Femoral component, please see additional Instructions for Use packaged with the mobile bearing and tibial implants.

The Oxford Femoral components are indicated for use with the Domed Lateral mobile bearings and tibial trays in the lateral compartment of the knee. The Domed Lateral tibial trays and mobile bearings are indicated for use in the lateral compartment of the knee. **The Domed Lateral tibial trays and mobile bearings are not approved for sale in the United States.**

CONTRAINDICATIONS
Contraindications include:
1. Infection, sepsis, and osteomyelitis.
2. Rheumatoid arthritis or other forms of inflammatory joint disease.
3. Insufficiency of the collateral, anterior or posterior cruciate ligaments which would preclude stability of the device.
4. Uncooperative patient or patient with neurologic disorders who are incapable of following directions.
5. Osteoporosis.
6. Metabolic disorders which may impair bone formation.
7. Osteomalacia.
8. Distant foci of infections which may spread to the implant site.
9. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.
10. Vascular insufficiency, muscular atrophy, neuromuscular disease.
11. Incomplete or deficient soft tissue surrounding the knee.
12. Charcot's disease.
13. A fixed varus deformity (not passively correctable) of greater than 15 degrees for Oxford Femoral Components when used with the Oxford Mobile bearing implants (medial application).
14. A flexion deformity greater than 15 degrees.

WARNINGS
1. Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components.
2. The single-piece polyethylene/metal-backed tibial components are designed to be used in treatment of low demand, less active sedentary patients. Patients that will remain active and/or overweight (BMI greater than 25) are not good candidates for single-piece polyethylene/metal-backed tibial components.
3. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.
4. Do not modify implants.
5. Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient. Furthermore, re-using an implant could cause patient contamination.
6. Malalignment or soft tissue imbalance can place inordinate forces on the components which may cause excessive wear to the tibial bearing articulating surfaces. Revision surgery may be required to prevent component failure.
7. Care is to be taken to ensure complete support of all parts of the device embedded in bone cement to reduce the risk of stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture and loosening due to cement failure has been reported.
8. The surgeon is to be thoroughly familiar with the implants, instruments and surgical technique, prior to performing surgery.
9. Patients should be warned of the impact of excessive loading that can result if the patient is involved in an occupation that includes substantial walking, running, lifting, or excessive muscle loading due to weight that place extreme demands on the knee and can result in device failure or dislocation.
10. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
11. The surgical technique should be followed. Deviations from the surgical technique could result in early loosening/failure of the device, or other adverse events as outlined in the following section. Clinical outcome may be affected by component positioning. Proper placement of the implant should take into consideration individual patient anatomy as well as surgeon preference. The surgical technique sets forth guidelines for placement of the knee system.
12. Increased activity as well as increased weight can lead to accelerated wear of UHMWPE inserts.

PRECAUTIONS
1. Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity, and 5) uncompartmental disease with correctable deformity with minimal to no ligament releases or inflammatory arthritis.
2. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissues have lower adhesion strength to cement than implants handled with clean gloves.
3. Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.
4. Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation and/or wear. All-polyethylene and single-piece, polyethylene/metal-backed implants may fracture due to loosening and/or migration/subsidence.
5. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned in advance of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.
6. Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from any other systems can result in inaccurate fit, sizing, excessive wear and device failure.
7. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement prior to surgery.
8. All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
9. Per ISO 14243-1, wear testing on devices comparable to the Oxford Fixed Lateral Bearing devices have been completed to 5 million cycles which represents 3 to 5 years of simulated walking.

POSSIBLE ADVERSE EFFECTS
The following complications have also been reported in the clinical literature for Partial and Total Knee arthroplasty designs and could potentially occur with the Oxford Partial Knee components.
1. Major surgical risks associated with anesthetic including, brain damage, pneumonia, blood clots, heart attack, and death.
2. Cardiovascular disorders including venous thromboses, pulmonary embolism, and myocardial infarction.
3. A sudden drop in blood pressure intraoperatively due to the use of bone cement.
4. Damage to blood vessels, hematoma, delayed wound healing and/or infection.
5. Temporary or permanent nerve damage may result in pain and numbness.
6. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process.
7. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
8. Early or late postoperative, infection, and allergic reaction.
9. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
10. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
11. Periarticular calcification or ossification, with or without impediment of joint mobility.
12. Inadequate range of motion due to improper selection or positioning of components.
13. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
14. Fatigue fracture of components can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
15. Fretting and crevice corrosion can occur at interfaces between components.
16. Wear and/or deformation of articulating surfaces.
17. Valgus-varus deformity.
18. Transient peroneal palsy secondary to surgical manipulation and increased joint movement has been reported following knee arthroplasty in patients with severe flexion and valgus deformity.
19. Patellar tendon rupture and ligamentous laxity.
20. Persistent pain.

Biomet® Oxford Partial Knee Implants in the Magnetic Resonance (MR) Environment

Biomet® Oxford Partial Knee implants are composed of non- ferromagnetic materials such as Titanium (Ti-6Al-4V), Cobalt Chrome (Co-Cr-Mo) and ultra high molecular weight polyethylene (UHMWPE).

Biomet has performed bench testing and numerical simulations on Oxford Partial Knee implants in a Magnetic Resonance Imaging (MRI) environment. These tests determined the non-clinical effects of MRI based on scientifically relevant characteristics of the Oxford components.

MR Safety Information
The Oxford Partial Knee is determined to be MR Conditional in accordance to ASTM F2503-08 Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use, as stated below:

Safety information for the use of MRI procedures (i.e. imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded MRI systems and/or the following specifications:
- Static magnetic field of 1.5-Tesla (1.5T) and 3.0-Tesla (3.0T)
- Spatial gradient field of 2500 -Gauss/cm or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15-minutes of scanning
- Normal mode of the MR system
- The effects of using MR conditions above these levels have not been determined.
- The effects of local RF transmit coils have not been tested and are not recommended in the area of the implant.
- Per good clinical practices, the patient's legs should not touch each other and arms and legs should not touch the side of the bore during scanning.

MR Information
1.5T MR system
64 MHz, GE Signa whole body coil from GE Signa MR (System, model number 46.256170G1 and serial number 10146M02, the magnet producing the static field was not present. RF power was applied continuous wave (CW) with an HP8648D (serial number 1715A06448) preamplifier and an ENI power amplifier (model 3200L, serial number 469).
- A temperature rise of 1.5°C or less was measured at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg for 15-minutes of RF power application.

3.0T MR system
128 MHz, GE Signa HDx 3T, Software Version=14LX/MR Software release 14.0.M5A.0826.b, General Electric Healthcare, Milwaukee, WI, active-shielded, horizontal field scanner.
- A temperature rise of 1.4°C or less was measured at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg for 15-minutes of RF power application.

Image Artifacts
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Distortion extended as much as 8 cm from the implant in image distortion tests performed according to ASTM F2119 in a 3.0 T GE Signa HDx MR system (Software Version 14LX/MR Software release: 14.0.M5A.0826.b). Therefore, it may be necessary to optimize MR imaging parameters for the presence of these implants.

Other: Testing indicated no known risks of magnetically induced displacement force or torque.

STERILITY
Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only. Do Not Reuse. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

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

Manufactured and Distributed by:
Biomet UK Ltd.
Waterton Industrial Estate
Bridgend CF31 3XA, UK

Manufactured and distributed in the United States by:
Biomet Orthopedics
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581 USA

CE mark on the package insert (IFU) is not valid unless there is a CE Mark on the product label.

Notes

This technique was prepared in conjunction with K. Berend, M.D., M. Berend, M.D., D. Mauerhan, M.D. Mr. C. Dodd and Prof. D. Murray. Zimmer Biomet does not practice medicine. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

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Legal Manufacturer
Biomet UK, Limited
Waterton Industrial Estate
Bridgend
CF31 3XA
UK

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