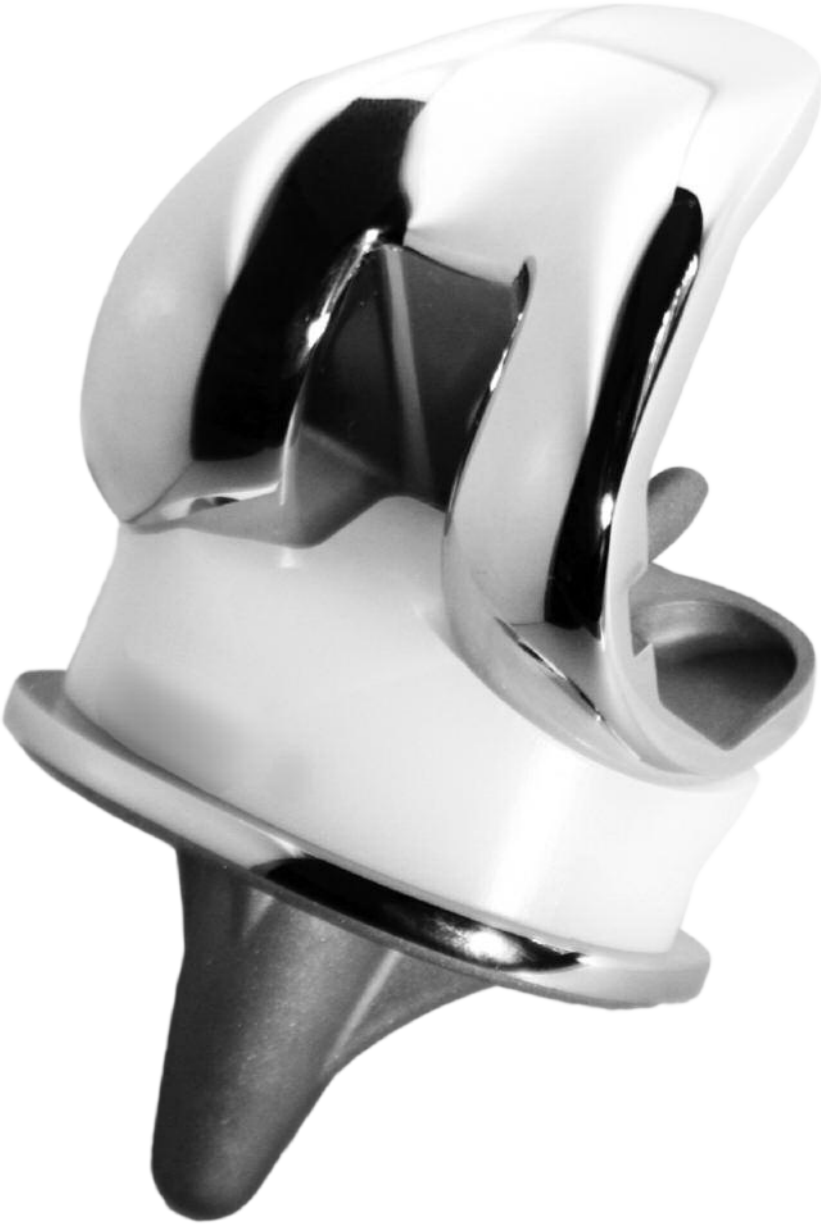
JointMedica

Birmingham Knee Replacement

SURGICAL TECHNIQUE



Introduction

The Birmingham Knee Replacement (BKR) is a rotating platform, posteriorly stabilized, primary Total Knee Replacement designed to satisfy specific issues important to both the patient and surgeon. It has been designed to satisfy the following criteria;

- Physiologically correct patella tracking
- Total joint stability from full extension to deep flexion; this is ensured through the use of highly congruent bearing surfaces, at both the tibiofemoral and p/s bearing surfaces.
- Anatomically accurate sizing with minimal bone resection
- An unprecedentedly low bearing wear rate, greatly improving anticipated prosthesis longevity
- Reduced implant inventory through optimised sizing; the entire spectrum of patient sizing is covered with six sizes of femoral and tibial components.
- Minimal but complete instrumentation, with patented, surgeon developed features and benefits.

Despite being granted full CE approval, initial use of the BKR was deliberately constrained to the development centre for two years. Only then was the BKR released for use by other orthopaedic surgeons. Following full commercial release, 15 respected UK Surgeons contributed to key data which resulted in the recent award of a 7A ODEP* rating.

Latest ODEP ratings can be found at www.odep.org.uk

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Preoperative Assessment

Successful TKA requires that both correct leg alignment and soft tissue tension be achieved. The BKR instrumentation has been designed to ensure as far as possible that these objectives are met. However, care must be taken by the surgeon to attain correct soft tissue tension; balance in flexion and extension must be achieved.

Long standing radiographs are required to determine both the mechanical and anatomic axes. The mechanical axis passes from the centre of the femoral head to the centre of the ankle, passing slightly medial to the centre of the knee.

The tibiofemoral angle, (valgus angle) can be measured, and usually varies between 5 and 10 degrees. This angle determines the distal femoral cut angle, and ensures correct limb alignment is restored.

X ray templates may be used to assess the required component sizes. The lateral view templates will give an indication of the femoral component required to avoid notching the femur. The anterior view template will indicate the size required to provide adequate coverage of the condyles. The tibial template anterior and lateral view templates will indicate the probable size of tibial component and thickness of bearing which will be required.

Surgical Instrument Preparation

All BKR surgical instruments must be cleaned and sterilised prior to use (see instrument cleaning and sterilisation instructions).

The following general purpose surgical instruments (not supplied) are additionally required:

- 0.50in/1.27mm Sagital saw blade
- Hudson Zimmer drill fitting
- Sagital saw
- Reciprocating saw.

All instruments should be checked for signs of damage and wear prior to use. Do not use any instrument that shows signs of damage, or of excessive wear.

Surgical Technique

Section 1. Tibial preparation

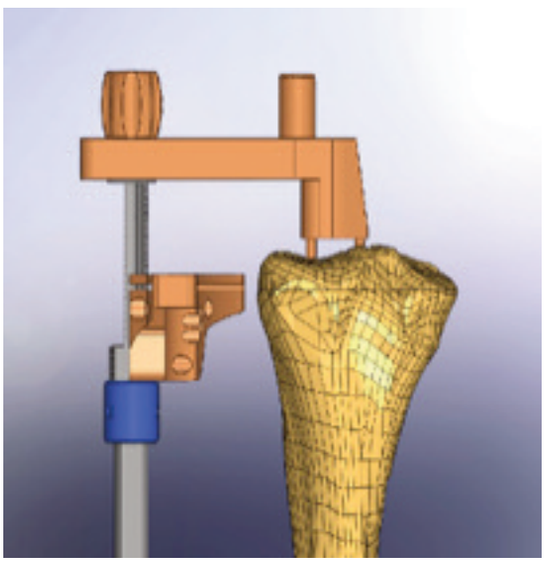
Objective: To prepare the tibia and secure the trial tibia in position (Steps 1 to 6).

Step 1. Tibial alignment

NOTE: The BKR requires a 0 degree posterior slope.

Assemble the extramedullary tibial alignment guide, ensuring that the correct left or right cutting block is attached, and locate the ankle clamp around the ankle. Impact the long spike of the spiked fixation rod to secure the assembly.

Adjust the extramedullary alignment assembly to be parallel to the long axis of the tibia. The extra medullary alignment assembly should align with the medial third of the tibial tubercle, and distally with the second toe. Impact the second spike of the proximal fixation rod once assessment has been completed.



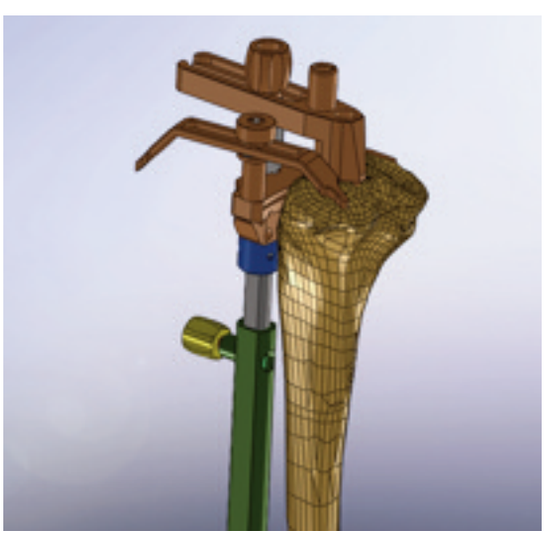
The position of the proximal e/m assembly may be adjusted using the thumbnut and slider of the spiked fixation rod.

Step 2.

Attach the tibial stylus to the tibial cutting block. Lower the cutting block until the stylus rests at the centre of the least deficient condyle.

Insert pins and screws as appropriate to secure the cutting block to the tibia. Remove the tibial jig, leaving the tibial cutting block securely fixed to the tibia.

An angel wing may be used to supply a visual check to that the bone cut is the correct thickness.

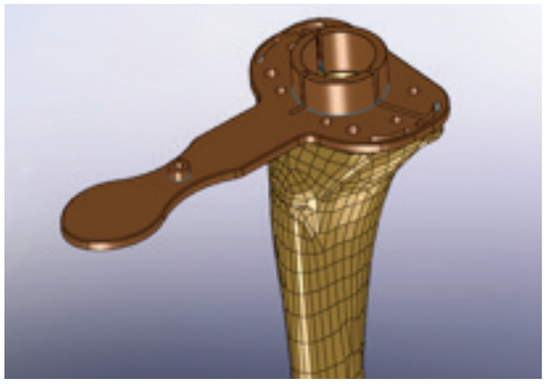


The stylus tip marked '10mm' indicates a 10 mm thick bone resection.

Surgical Technique

Step 3.

Select the tibial template and assess its position to achieve maximum tibial coverage. Once the tibial template is positioned correctly, secure the tibial template in place with headed pins.



If required, locate the pilot drill guide bush onto the tibial trial, and drill the tibial stem pilot hole using the tibial starter drill.

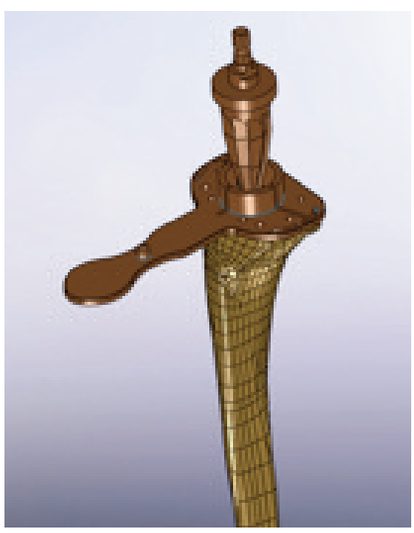
Step 4.

Remove the pilot drill guide bush, and using the tibial cone reamer, prepare the resected tibia to suit the tibial component stem.

Note: The tibial templates are individually adjusted to ensure the tibial cone reamer finishes the tibia to match the selected size of tibial component.

Using a reciprocating saw, minimal introducer slots are made in the proximal tibia through the anterior, medial, and lateral slots of the tibial trial.

There are teeth on the corresponding fins of the tibial component, which on impaction, open the slots to finished size.

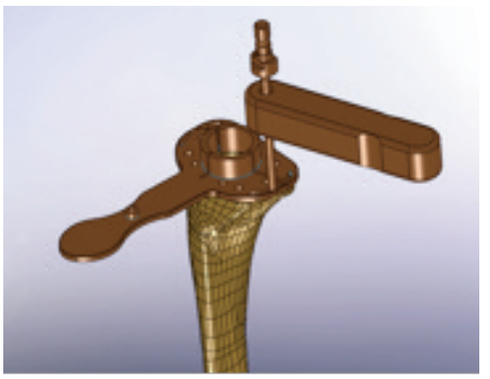


Surgical Technique

Step 5.

If the mediolateral margins of the resected tibia are highly sclerotic, the trochar drill can be used to prepare these areas to more easily receive the tibial component cement pressurizing rim.

This is an optional step, made at the surgeons discretion.



Step 6.

Remove the tibial template. Secure the correct tibial trial component to the trial introducer, and locate the trial component into the resected tibia. Once the trial is accurately aligned, impact the trial tibial component into place.

The trial tibial component remains in place for the duration of the procedure.

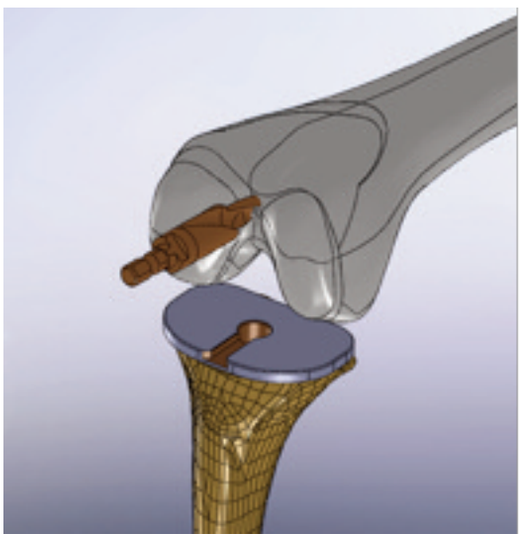
Surgical Technique

Section 2. Femoral facet cut preparation

Objective: To prepare the femoral facet cuts, including the patella sulcus rough cut. To assess the soft tissue balance in flexion. (Steps 1 to 10).

Step 1.

First trim all peripheral osteophytes to restore the distal femur to near normal anatomical shape.



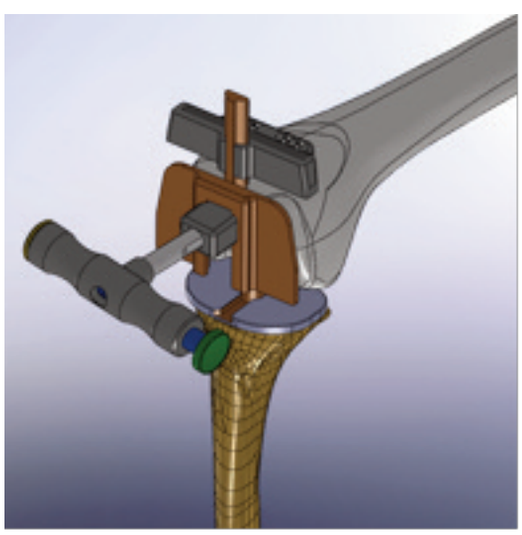
Step 2.

Using the starter drill, open the intramedullary canal. Place the tip of the drill in the centre of the intercondylar notch approximately 1cm anterior to the emergence of the posterior cruciate ligament.

Step 3.

Assemble the 3, 5, or 7 degree alignment bush, intramedullary rod, tee handle, and distal reference plate.

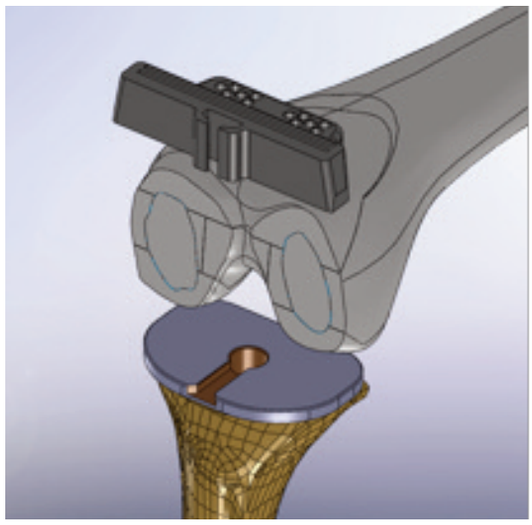
Introduce the i/m rod into the canal, and locate the distal reference plate against the distal condyles. Position the distal cutting block on the arm of the distal reference plate, and secure it in position with shoulder pins and self tapping screws.



Surgical Technique

Step 4.

Remove the i/m rod, distal reference plate, and alignment bush. Make the distal cut through the most distal slot. This will resect 9mm of bone, equivalent to the femoral component distal condyle thickness.



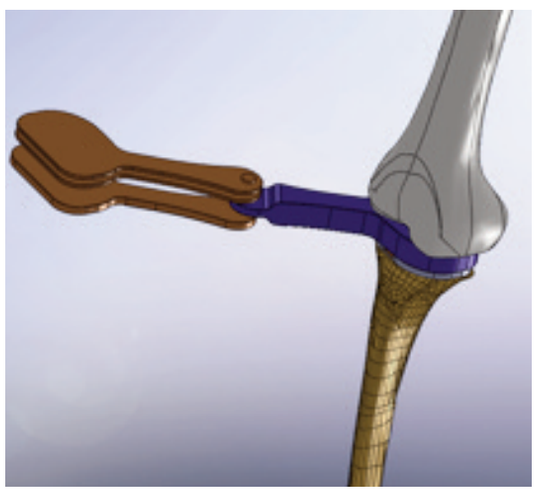
Step 5.

Check the ligament balance in extension.

The extension gap at this point should be 19mm (the combined thickness of the 4mm tibial tray, 6mm tibial insert, and 9mm distal femoral condyles).

Insert the extension gap spacer assembly as shown, and manipulate the leg to assess the soft tissue tension and balance across the joint. The extension gap should be rectangular at this point.

The bilateral soft tissues must be balanced where there is slackness or tightness at the lateral and medial margins. The thickness of the extension gap spacer block assembly can be adjusted, and will indicate the appropriate thickness of tibial insert, subject to reassessment at trial reduction.



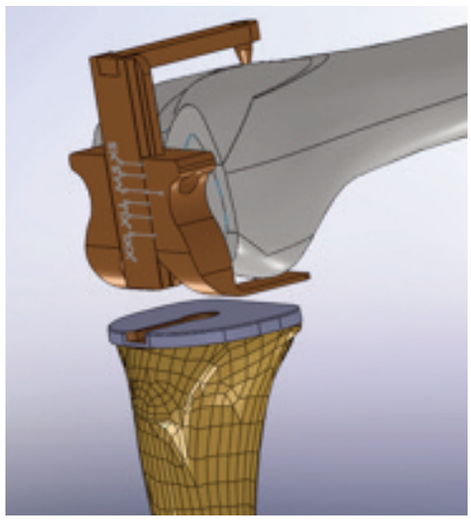
Surgical Technique

Step 6.

Femoral sizing.

Locate the femoral sizer in position, with the posterior arms located against the posterior condyles. Adjust the sizer until the anterior stylus touches the femur proximal to the articular surface of the patella trochlea.

The femoral sizer will indicate the size of femoral component required.

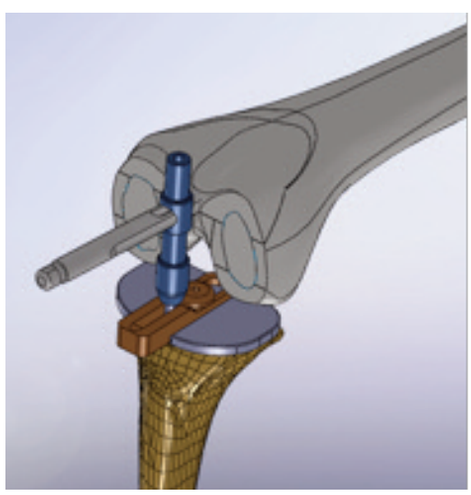


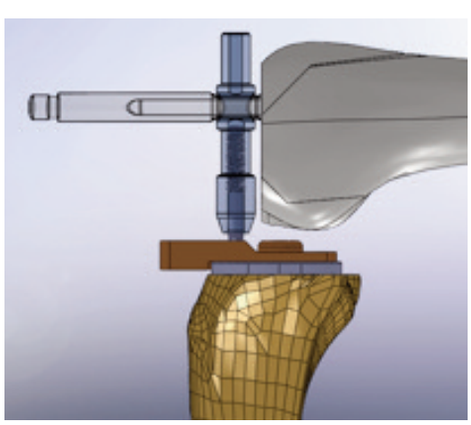
Step 7.

Assemble the Birmingham block distraction body assembly.

There is one distraction body, and 3 sizes of distraction screws. They are sized Small, Medium, and Large, and are intended to approximate the expected range of anatomy.

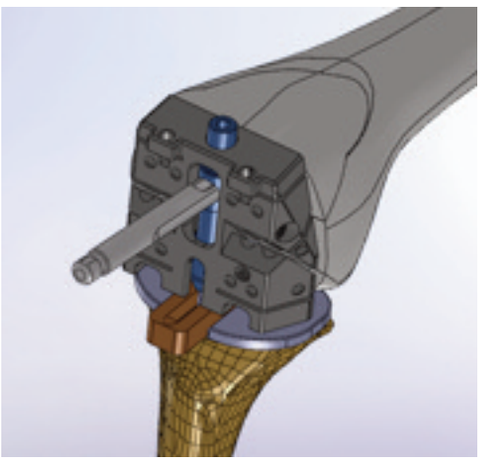
The distraction assembly assists the surgeon in assessing ligament balance and cutting block alignment and position before committing to any definitive bone cuts.





Surgical Technique

Step 8.

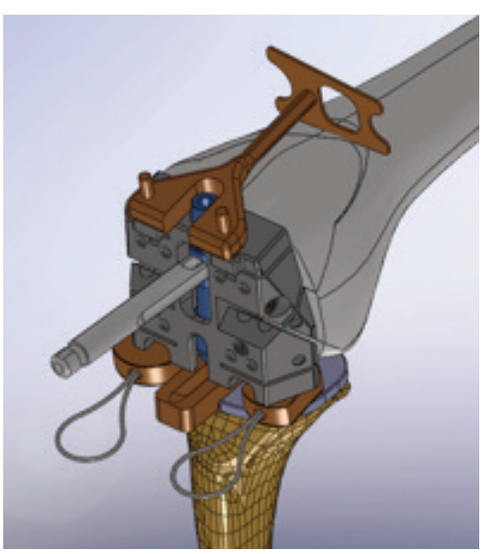


Mount the cutting block onto the distraction body assembly.

With the knee in 90 degrees of flexion, the cutting block is mounted onto the distraction body assembly. If it is determined that either a smaller or larger cutting block is required, the chosen block may be easily removed, and another located onto the distraction body assembly.

Note: The Birmingham block anterior and posterior chamfer cuts, and the posterior condyle cuts are definitive cuts. The patella sulcus cut is a rough cut. The definitive patella sulcus cut is produced through a cutting slot in the trial femoral component, once coronal plane component positioning has been confirmed.

Step 9.



Anterior reference check and insertion of magnetic spacers.

Once the cutting block has been mounted, 6mm magnetic spacers are inserted between the cutting block and superior surface of the tibial component, and the anterior referencing instrument is located in two holes at the anterior edge of the cutting block. The superior edge of the referencing instrument indicates where the most superior edge of the patella sulcus cut will emerge. The cutting block position can be adjusted accordingly. The positional relationship of the patella sulcus to the posterior facet cuts can then be assessed

Through adjustment of the distraction assembly, (via the screw located within the distraction assembly) collateral soft tissue balance can be assessed.

An angel wing may be used to assist in visual assessment of cutting block positioning.

The cutting block is fixed in position with shoulder pins and screws.

Once the position of the cutting block has been confirmed, the facet cuts can be made.

Surgical Technique

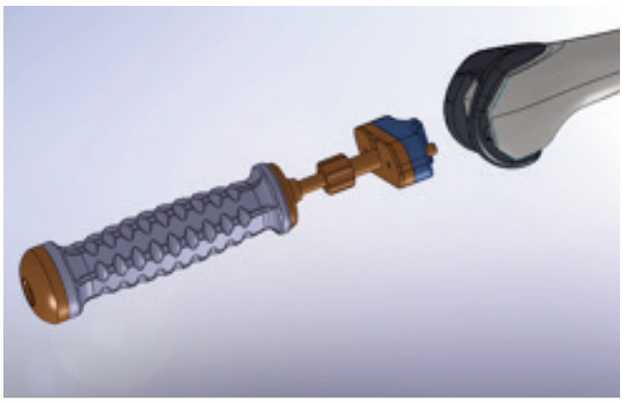
Step 10.

Impact the trial femoral component .

Identify the correct trial femoral and matching introducer plate. Assemble the introducer, and fix to the trial femoral component.

The trial introducer pins are designed to press fit into matching holes in the trial femoral component.

Impact the trial femoral component into position. The trial femoral component coronal plane position can be adjusted to achieve optimum coverage



Surgical Technique

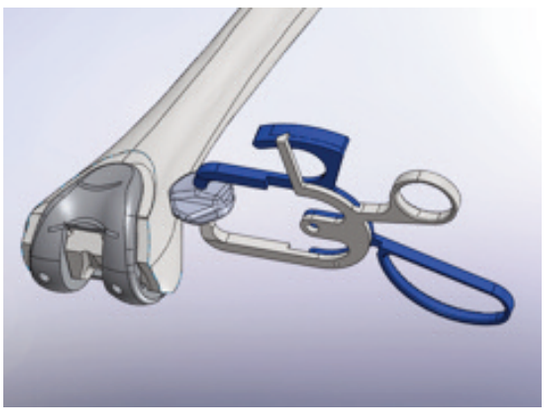
Section 3. Patella preparation

The BKR has a highly developed range of patella components, and patented patella tracking instrumentation. This combination offers unprecedented intraoperative opportunity to optimize the patellofemoral kinematics.

Step 1.

Measure the patella thickness.

Note: The patella component thickness is 9.5 mm.



Step 2.

Resect the patella.

Remove any peripheral osteophytes, returning the patella to a near normal anatomy.

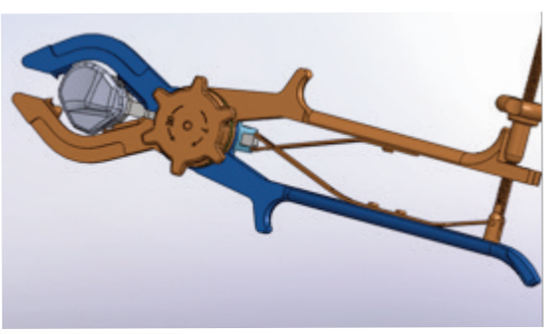
The resection level and resulting cut surface are important factors in correctly resurfacing the patella. The articulating surface is removed with the articular surface exposed by everting laterally.

Having measured the thickness of the patella, set the patella clamp stylus to resect 9mm of the articular aspect of the patella.

Locate the jaws of the patella resection clamp around the patella, and squeeze the teeth onto the patella.

Visually confirm the attitude of the patella clamp with respect to the patella articular surface.

Firmly lock the clamp in place, and resect the patella.



Surgical Technique

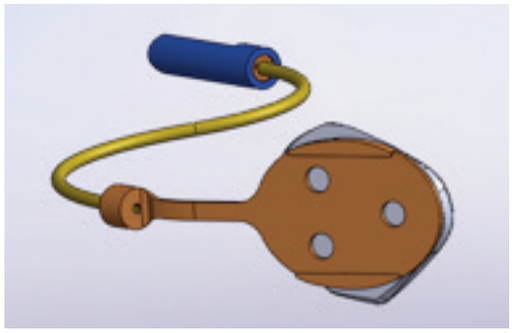
Step 3.

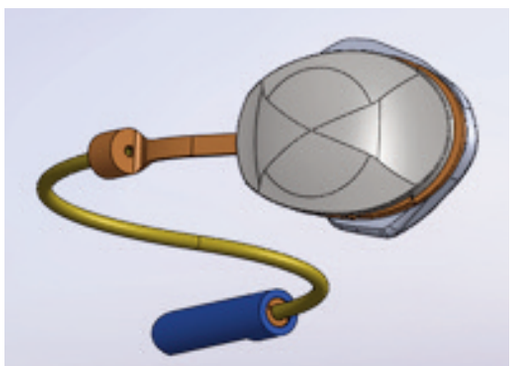
Patella tracker selection.

Select the patella tracker base plate which provides optimum coverage of the exposed patella resected surface.

Pin the patella tracker base plate to the resected patella.

Insert the correct size 5mm offset trial patella tracker flexible wire into the base plate, and confirm the assembly is fully mobile; the button should freely translate in the coronal plane.

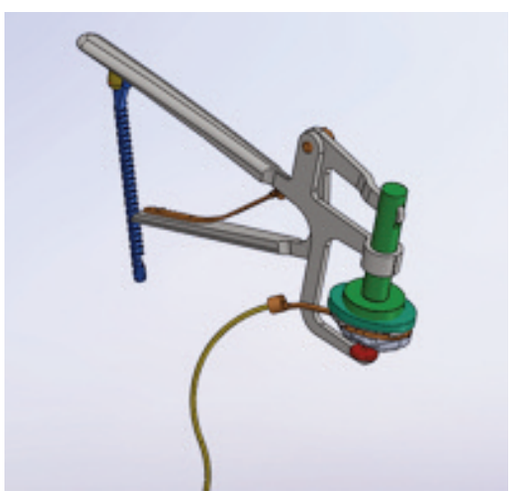




Step 4.

With the button in place, apply the patella compressor across the patella button. Compress the patella tracker baseplate spikes into the exposed bone cut surface.

Reduce the joint with patella tracker in place, and suture the edges together. This will replicate the effect of the soft tissue tension on the medial side of the patellofemoral joint.



Surgical Technique

Step 5.

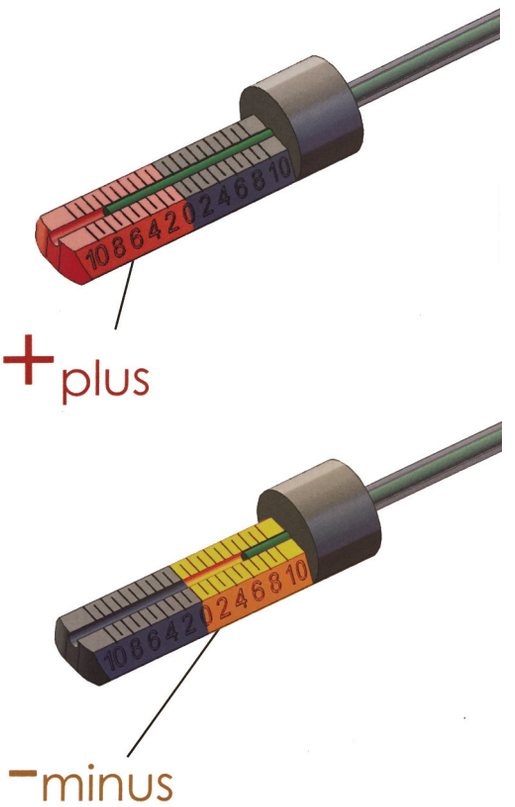
Flex and extend the trial knee implants taking note of the dynamic measurements from the patella tracker.

+ plus

- Lateralise the femoral component
- Increase patella offset
- If possible, medialise patella button

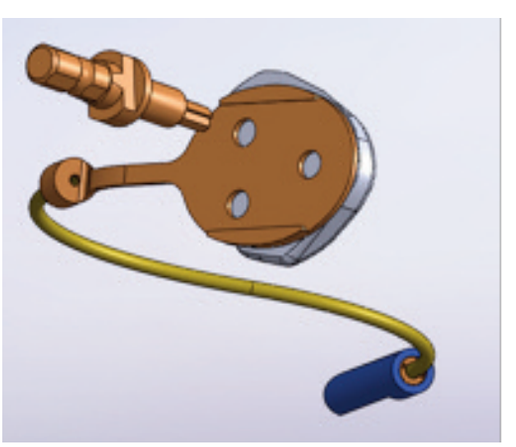
- minus

- Medialise femoral component
- Use smaller offset patella button
- If possible, lateralise patella button



Step 6.

Drill the patella button cement holes using the patella peg drill.



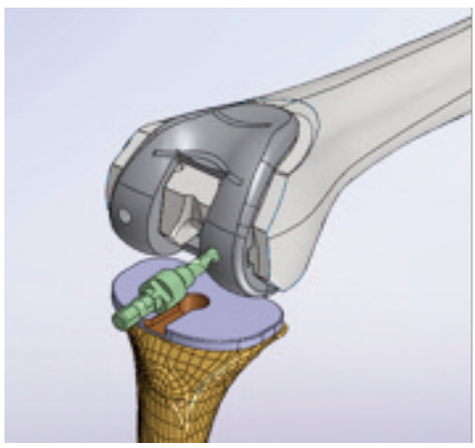
Surgical Technique

Section 4. Prepare the femoral box cuts

Step 1.

Femoral peg hole preparation.

Having confirmed the position of the femoral component , drill the femoral component distal peg holes using the femoral peg drill.



Step 2.

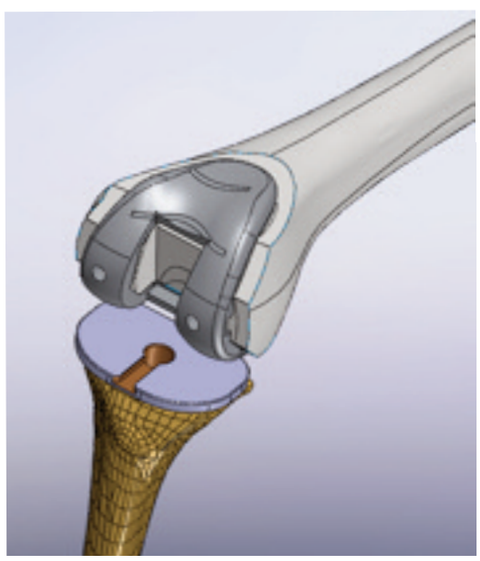
Finish the femoral resection.

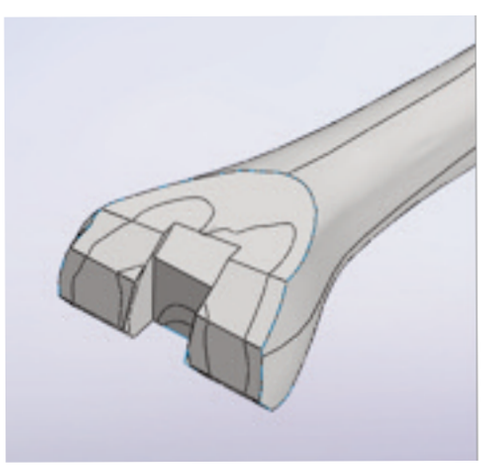
Note: The trial femoral component should be firmly fixed to the host bone. If required, fixation screws can be introduced through two holes in the patella sulcus.

Using a .050in/1.27mm sagital saw blade, resect the femur in the following order;

- Superior box cut. To help guide the blade, engage the blade with the medial and lateral slots at the anterior aspect of the i/c box. At full depth, the blade must engage with the corresponding full width slot in the i/c box, cut into the cam at the back of the trial femoral component.
- Cut the medial and lateral vertical edges of the i/c box. The i/c wedge of bone may be removed.
- Using the sagital saw, resect the patella sulcus.
- Using a reciprocating saw, make the patella sulcus cut.
- Be sure to remove posterior osteophytes using a curved osteotome.
- Remove the trial femoral component. Using the reciprocating saw, make the shallow cuts which define the margins of the recess for the patella flange web.

A bone block can now be used to block the i/m canal access hole.

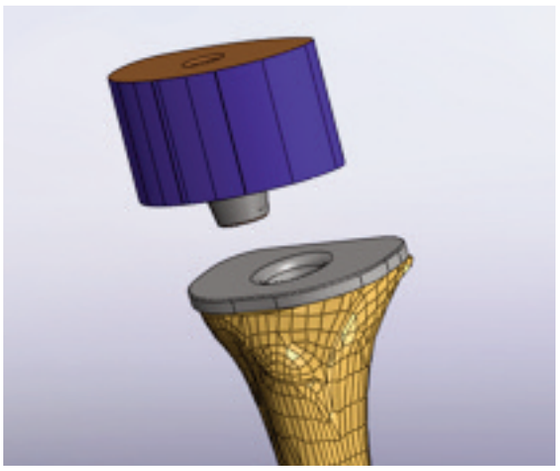




Surgical Technique

Section 5. Insert the definitive components and trial reduction.

Step 1.



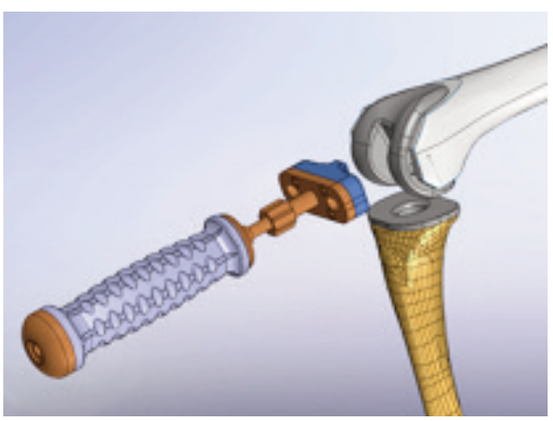
Insert the tibial component.

Using pressurised lavage, thoroughly clean the prepared surfaces, and dry. Apply cement to both the tibial plateau, and the underside of the tibial component.

Using the dedicated tibial component impactor block, introduce the tibial component, and impact fully. Take care not to scratch the tibial component articular surfaces.

After impaction remove all extruded surplus cement.

Step 2.



Insert the definitive femoral component.

Using pressurised lavage, thoroughly clean the prepared surfaces, and dry. Apply cement to both the prepared femoral surfaces, and the internal surfaces of the femoral component.

Introduce the femoral component, and using the femoral component impactor, impact fully. Take care not to scratch the femoral component articular surfaces.

After impaction remove all extruded surplus cement. Take care to remove excess cement from the posterior condyles, and the superior aspect of the cam.

After impaction of both components, at trial reduction, the cement may be pressurised by extending the leg to 0 degrees, or through to slight hyperextension.

Surgical Technique

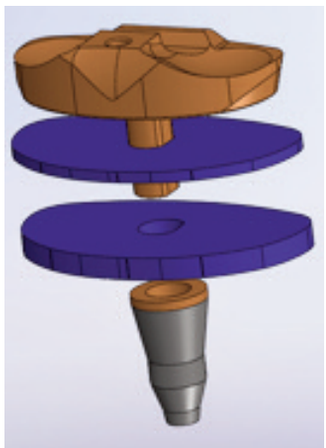
Step 3.

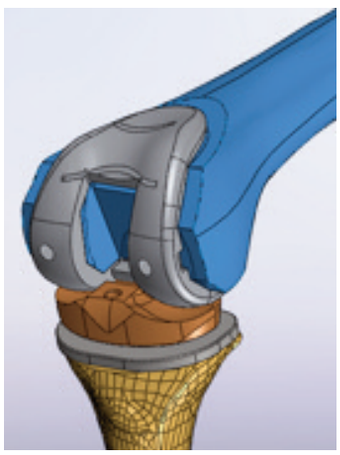
Assemble the trial bearing.

The bearing thickness ranges from 10mm to a maximum of 20mm.

2.5mm and 5mm spacers are available which increase the bearing thickness up to 20mm in 2.5 and 5 mm increments.

Slide the bearing cone onto the bearing stem. Locate the trial stem into the tibial tray, and reduce the joint.





Step 4.

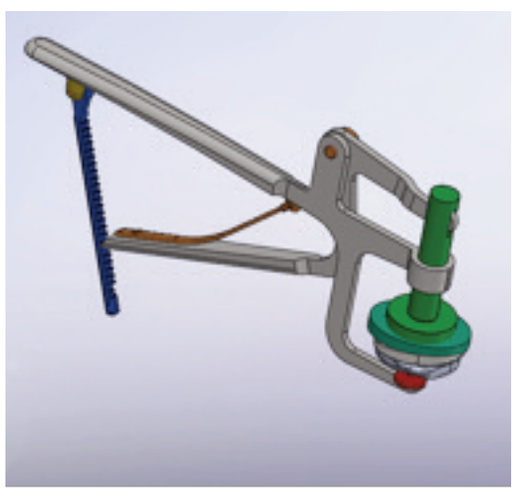
Cement the patella.

Thoroughly clean and dry the prepared surface. Apply bone cement to the prepared surface and the patella implant. Identify the drilled peg holes in the patella, and press the patella implant into place.

Apply the cement clamp and apply sufficient pressure to extrude any excess cement. Reduce the joint.

Check the patella tracking with the patella in place. It should slide freely in the trochlea groove without external manipulation or assistance (the no thumbs test).

Ensure there is an unrestricted range of motion at the tibiofemoral joint, and free rotation at the tibal to bearing interface. Manipulate the joint to confirm tibiofemoral stability.



Step 5.

Procedure Completion.

Closure, drains, and dressing, are subject to the surgeons' preference.

Appendix

Instrument Cleaning & Sterilisation Instructions

General Instrument Care, Handling & Sterilisation

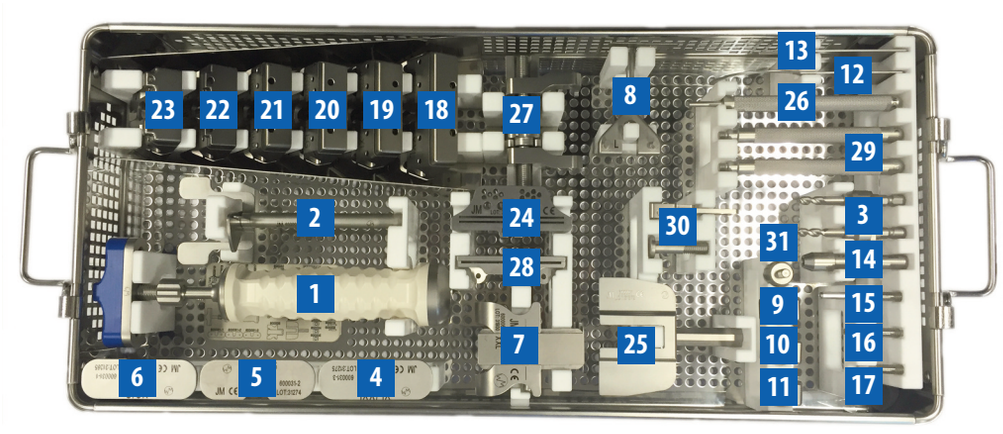
These special instructions apply for the proper care and handling of the instruments to ensure their longevity.

- Personal protective equipment should be worn at all times when handling contaminated or potentially contaminated instruments.
- No individual BKR instruments require disassembly for cleaning and sterilisation, but please ensure that any instruments which have been assembled together for surgery are disassembled, and the individual instruments are placed in their correct location within the supplied instrument cases, prior to cleaning and sterilisation.
- Exercise caution when handling instruments with sharp edges or points.
- To facilitate cleaning of the BKR instruments, where possible, do not allow contaminating substances (such as blood, body fluids, bone and tissue debris, saline or disinfectant) to dry on the BKR instruments prior to cleaning.
- Use a low-foaming, neutral pH detergent, designed for cleaning surgical instruments, to clean the BKR instruments (both manual and ultrasonic cleaning). Do not use a multipurpose detergent, as this may damage the instrument surface finish.
- Do not use metal brushes, scouring pads, or abrasive cleaners to clean the BKR instruments, as these may damage the instrument surface finish. Use only soft-bristled nylon brushes or pipe cleaners to clean the BKR instruments.
- Rinse cleaned BKR instruments in clean water, to remove any residual detergent prior to instrument sterilisation. Do not use an acid rinse or bleach on the BKR instruments, as these may damage the instrument surface finish.
- Use a syringe or water jet to flush out difficult to reach areas of the instruments and mated surfaces.
- Cleaned BKR instruments must be sterilised prior to use, in a steam autoclave. It is recommended to sterilise the BKR instruments in their correct locations within the supplied instrument cases, using the following steam sterilisation cycle parameters:

  UK: pre-vacuum cycle, temp.: 134° - 137° for a minimum holding time of 3 minutes, and a drying time of 30 minutes.

Instrument Tray Layouts

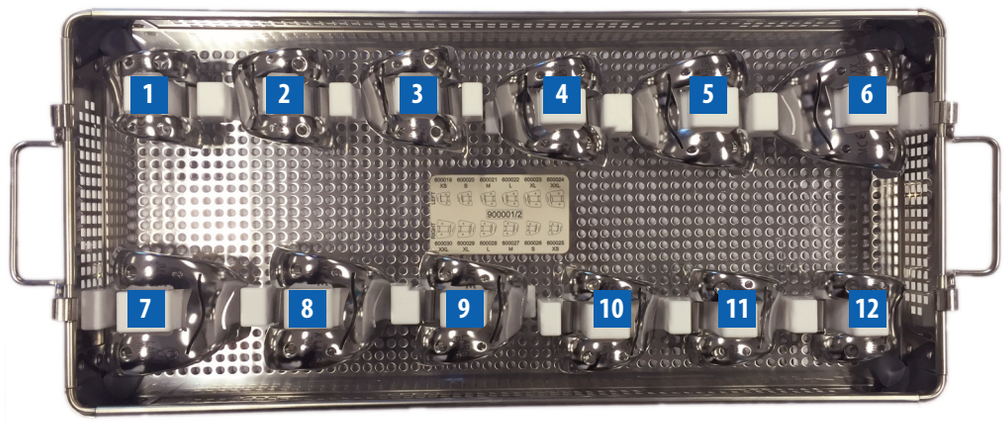
Femoral Tray Base (900001)



NUMBER	QTY	CATALOGUE NUMBER	DESCRIPTION
1	1	600031	Femoral Impactor
2	1	600002	External Rotation Assembly
3	1	600034	Femoral Peg Drill
4	1	600031-3	Impactor Trial Implant Plate XL/XXL
5	1	600031-2	Impactor Trial Implant Plate M/L
6	1	600031-1	Impactor Trial Implant Plate XS/S
7	1	600006	Femoral Sizing Jig
8	1	600003	Anterior Reference Assembly
9	1	600040	Valhus Block 3
10	1	600004	Valgus Block 5
11	1	600005	Valgus Block 7
12	1	600033	Angel Wing 2
13	1	600041	Angel Wing
14	1	600001	Distraction Body
15	1	600011	Distraction Rod Long
16	1	600010	Distraction Rod Medium
17	1	600009	Distraction Rod Short
18	1	600017	XXL Contour Cutting Block
19	1	600016	XL Contour Cutting Block
20	1	600015	Large Contour Cutting Block
21	1	600014	Medium Contour Cutting Block
22	1	600013	Small Contour Cutting Block
23	1	600012	XS Contour Cutting Block
24	1	600008	Distal Resection Block
25	1	600007	Distal Femoral Reference Plate
26	1	600032	Tommy Bar
27	1	600032	Femoral Extractor Clamp
28	1	800017	Distal Re Cut Plate
29	2	600042	Cutting Block Handle
30	1	500053	Rotation Device (2 Parts)
31	1	600043	Block Extractor
32	1	900001	Femoral Tray Base Plate

Instrument Tray Layouts

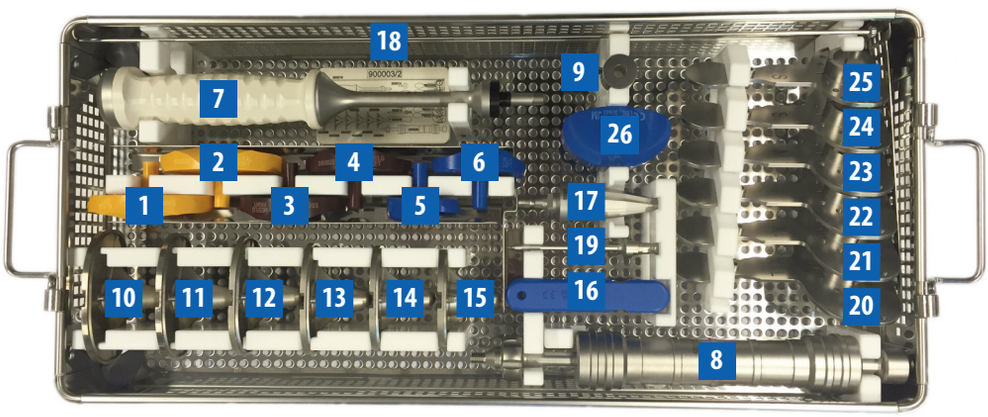
Femoral Tray Insert (90002)



NUMBER	QTY	CATALOGUE NUMBER	DESCRIPTION
1	1	600019	X Small combined box cutting block / femoral trial left
2	1	600020	Small combined box cutting block / femoral trial left
3	1	600021	Medium combined box cutting block / femoral trial left
4	1	600022	Large combined box cutting block / femoral trial left
5	1	600023	X Large combined box cutting block / femoral trial left
6	1	600024	XX Large combined box cutting block / femoral trial left
7	1	600025	X Small combined box cutting block / femoral trial right
8	1	600026	Small combined box cutting block / femoral trial right
9	1	600027	Medium combined box cutting block / femoral trial right
10	1	600028	Large combined box cutting block / femoral trial right
11	1	600029	X Large combined box cutting block / femoral trial right
12	1	600030	XX Large combined box cutting block / femoral trial right
13	1	900007	Femoral Tray Lid
14	1	900002	Femoral Tray Insert
15	1	600030	Femoral Case

Instrument Tray Layouts

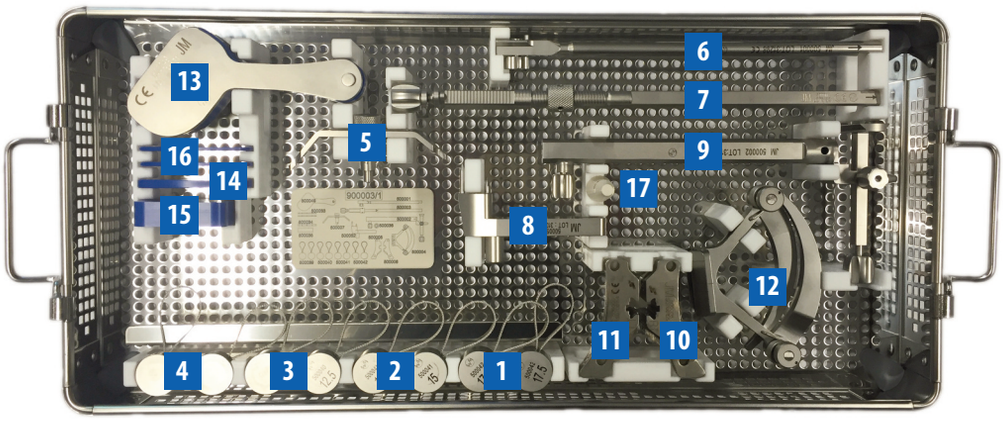
Tibial Tray Base (900003)



NUMBER	QTY	CATALOGUE NUMBER	DESCRIPTION
1	1	500032	XL/XXL 10mm Trial Bearing Right
2	1	500031	XL/XXL 10mm Trial Bearing Left
3	1	500030	Medium/Large 10mm Trial Bearing Right
4	1	500029	Medium/Large 10mm Trial Bearing Left
5	1	500028	XS/S 10mm Trial Bearing Right
6	1	500027	XS/S 10mm Trial Bearing Left
7	1	500019	Tibial Trial Impactor Handle
8	1	500020	Tibial Slap Hammer
9	1	500014	Tibial Template Pilot Drill Guide Bush
10	1	500059	XXL Tibial Trial
11	1	500058	XL Tibial Trial
12	1	500057	Large Tibial Trial
13	1	500056	Medium Tibial Trial
14	1	500055	Small Tibial Trial
15	1	500054	XS Tibial Trial
16	1	500048	Trocar Drill Guide
17	1	500017	Cone Reamer
18	1	500016	Tibial Template External Alignment Rod
19	1	500015	Tibial Trocar Drill
20	1	500013	XX Large Tibial Template
21	1	500012	X Large Tibial Template
22	1	500011	Large Tibial Template
23	1	500010	Medium Tibial Template
24	1	500009	Small Tibial Template
25	1	500008	XS Tibial Template
26	1	500050	Tibial Implant Impactor with Locator
27	1	900003	Tibial Trial Base Plate

Instrument Tray Layouts

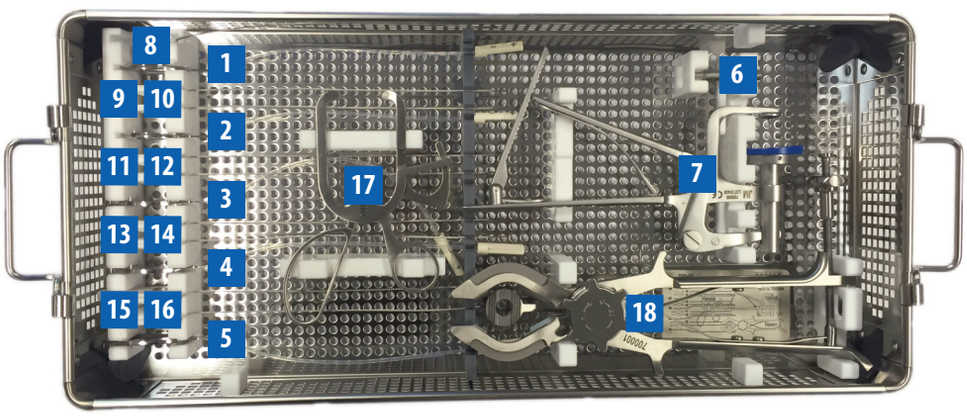
Tibial Tray Insert (900004)



NUMBER	QTY	CATALOGUE NUMBER	DESCRIPTION
1	2	500042	Magnetic Spacer 17.5mm
2	2	500041	Magnetic Spacer 15mm
3	2	500040	Magnetic Spacer 12.5mm
4	2	500039	Magnetic Spacer 10mm
5	1	500007	Proximal Tibial Reference Guide
6	1	500001	Transformer Rod
7	1	500003	Telescoping Rod
8	1	500052	Proximal Slide Bar
9	1	500002	E.M. Tibial Cut Guide
10	1	500006	Tibial Cutting Block Right
11	1	500005	Tibial Cutting Block Left
12	1	500004	Ankle Clamp
13	1	500049	Spacer Assembly
14	1	500034	5mm Trial Bearing Spacer
15	1	500035	15mm Trial Bearing Spacer
16	2	500033	2.5mm Trial Bearing Spacer
17	1	500036	Trial Bearing Cone
18	1	900004	Tibial Tray Insert
19	1	900008	Tibial Tray Lid
20	1	900031	Tibial Case

Instrument Tray Layouts

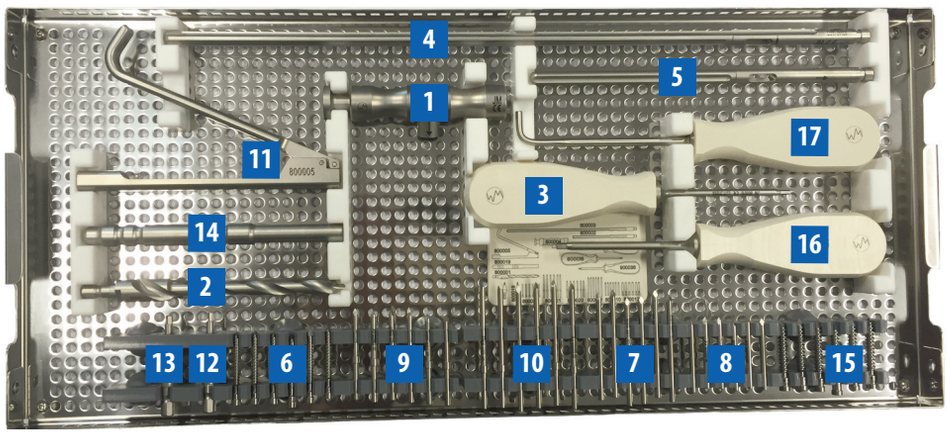
Ancillaries Tray Base (900005)



NUMBER	QTY	CATALOGUE NUMBER	DESCRIPTION
1	1	700006	Patella Tracking Device X Small
2	1	700007	Patella Tracking Device Small
3	1	700008	Patella Tracking Device Medium
4	1	700009	Patella Tracking Device Large
5	1	700010	Patella Tracking Device X Large
6	1	700004	Patella Drill
7	1	700005	Patella Cementing Clamp
8	1	700012	XS 5mm Offset Trial Assembly
9	1	700013	Small 5mm Offset Trial Assembly
10	1	700014	Small 7mm Offset Trial Assembly
11	1	700015	Medium 5mm Offset Trial Assembly
12	1	700016	Medium 7mm Offset Trial Assembly
13	1	700017	Large 5mm Offset Trial Assembly
14	1	700018	Large 7mm Offset Trial Assembly
15	1	700019	X Large 5mm Offset Trial Assembly
16	1	700020	X Large 7mm Offset Trial Assembly
17	1	700002	Patella Sizing Caliper
18	1	700001	Patella Resection Clamp
19	1	900005	Ancially Tray Base Plate

Instrument Tray Layouts

Ancillaries Tray Insert (900006)



NUMBER	QTY	CATALOGUE NUMBER	DESCRIPTION
1	1	800004	T Handle
2	1	800001	Starter Drill
3	1	800016	Hex Driver 2.5mm
4	1	800003	IM Rod Long
5	1	800002	IM Rod Short
6	6	800023	Femoral Trial Screw
7	6	800011	Plain Pin Long
8	6	800010	Plain Pin Short
9	6	800021	Headed Pin Long
10	6	800020	Headed Pin Short
11	1	800005	Pin Puller
12	1	800018	2.5 Hex Driver (Magnetic)
13	1	900011	3.5mm Hex Driver (Magnetic)
14	1	800019	Pin Impactor
15	6	800012	40mm Threaded Pin 5mm Diameter
16	1	900036	Hex Driver 3.5mm
17	1	900035	Trial Bearing Extractor
18	1	900006	Ancillaries Tray Insert
19	1	900009	Ancillaries Tray Lid
20	1	900033	Ancillaries Case

Instructions for Use

Birmingham Knee Replacement

Carefully read all instructions and be familiar with the surgical technique prior to use.

Description and Intended Use
The Birmingham Knee Replacement (BKR) is a rotating platform, posterior stabilised, primary total knee prosthesis, for use when both cruciate ligaments are excised.
The BKR consists of femoral, tibial baseplate, mobile tibial bearing and patella components, all of which are designed to be permanently implanted together, to achieve total reconstructive replacement of the knee joint.
The BKR implant components are available in a range of sizes to accommodate anatomical variation.
The femoral and tibial baseplate components are designed for cemented fixation only, using polymethyl methacrylate (PMMA) bone cement.

Materials
Femoral and tibial baseplate components are made from cobalt chrome molybdenum alloy that complies with ISO 5832-4.
Patella and tibial bearing components are made from compression-moulded ultra high molecular weight polyethylene (UHMWPE) that complies with ISO 5834-2.

Indications
The BKR is indicated for use in patients with severe knee pain and disability due to:
- degenerative osteoarthritis, rheumatoid arthritis, or post-traumatic arthritis;
- post-traumatic loss of knee joint configuration and function; or,
- moderate valgus, varus, or flexion deformities of the knee.

Contraindications
- Previous or current history of infection in the affected joint, and/or local or systemic infection which may affect the prosthetic joint.
- Revision of failed previous total knee arthroplasty.
- Insufficient bone stock on femoral or tibial surfaces.
- Skeletal immaturity.
- Neuropathic arthropathy.
- Osteoporosis or any loss of musculature or neuromuscular disorder that compromises the affected limb.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity - an excessively overweight or obese patient can impose forces on the prosthesis which can lead to failure of implant fixation, or failure of the implant itself.

Warnings
- The BKR implants are for single use only and must not be reused. Reuse presents a risk of infection and a risk that implant performance may be adversely affected.
- Never reinsert an articular component that has been inserted previously, as its performance may be adversely affected.
- Polished bearing surfaces must not come into contact with hard or abrasive surfaces.
- Bearing surfaces must be clean and free of cement, or other debris prior to assembly.
- Avoid notching, scratching, or striking the implant components.
- Do not implant the femoral or tibial baseplate components without bone cement.
- Do not use the BKR implants:
  - for purposes other than the labelled indications;
  - if damage is found or caused during setup or insertion; or,
  - in conjunction with components from other knee systems.
- Avoid improper positioning or alignment of the BKR implants. The risk of implant failure is higher with inaccurate implant positioning or alignment due to unusual stress conditions which may occur, leading to a reduction in the life of the implant. Refer to the surgical technique guide for information specific to the recommended positioning and alignment of the BKR implants.

Precautions
- Before clinical use the surgeon must thoroughly understand all aspects of the surgical procedure and the limitations of the BKR implants.
- Patients should be advised that the useable

life of the BKR implants is not indefinite and can be affected by various biological, mechanical and physiological factors.
- Patients should be instructed in the limitations of the implants, including potential adverse effects on the implants caused by excessive loading, as a result of patient weight or activity. Patients should be instructed to govern their activities accordingly.
- Use only surgical instruments from the dedicated BKR instrument set, as these have been specifically designed to aid in accurate insertion of the BKR implants.
- Selection of the appropriate size of implant components to use for a patient is the responsibility of the surgeon.
- Care should be taken to ensure appropriate size matching of BKR implant components. An implant size matching chart is provided to assist the user. Use of mismatched implant components may lead to poor surface contact and could result in pain, increased wear, implant instability, loss of joint function and reduced implant life.
- Selection of the thickness of the mobile tibial bearing is at the surgeons discretion - thicker bearing components may be required if the patient is young, heavy and/or physically active.

Possible Adverse Effects
- Loosening and/or disassembly of implants.
- Fracture of / damage to the implants.
- Soft tissue impingement or damage.
- Joint instability and/or dislocation.
- Malalignment of the implants.
- Bone fracture.
- Nerve damage.
- Infection.
- Soft tissue swelling or inflammation.
- Leg length discrepancies.
- Knee joint stiffness and/or limited range of motion.
- Delayed wound healing.
- Temporary or permanent neuropathy.
- Pain.
- Cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction.
- Metal sensitivity.
- Corrosion of metal components.
- Osteolysis, caused by wear debris from polyethylene components.

Sterility and Shelf Life
The BKR implants are supplied in a sterile condition (sterilised by gamma irradiation) and have a shelf life of 5 years when stored unopened, under ambient conditions. Implant packages should be inspected prior to use. Do not use an implant if the sterile packaging is open or damaged, or if the indicated expiry date has been exceeded. Metal femoral and tibial baseplate implant components that have been opened but have not been used may be re-sterilised once (the implants must be returned to JointMedica for re-sterilisation). Patella and mobile tibial bearing implant components composed of UHMWPE must not be re-sterilised.

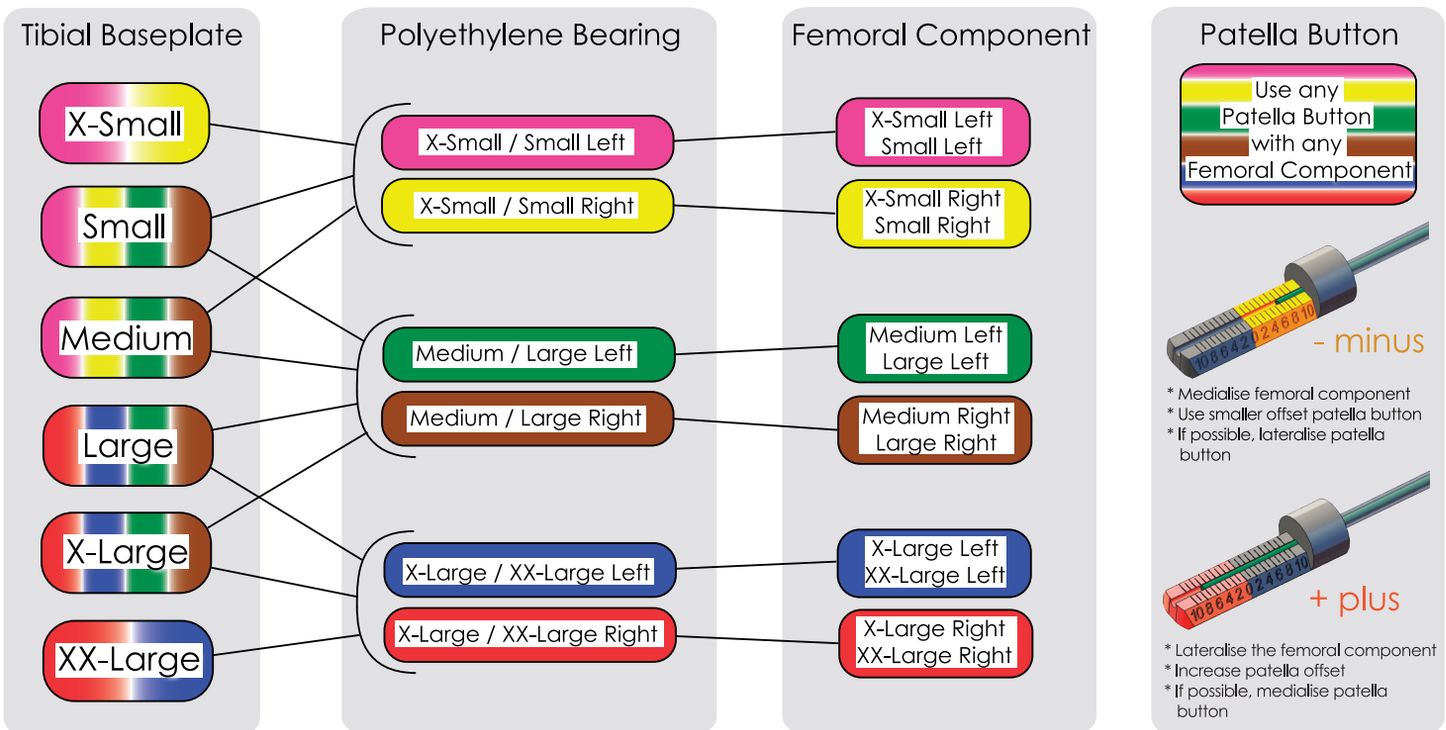
Manufacturer
JointMedica Limited
Unit 3 - Ball Mill Top Business Park
Main Road
Hallow
Worcestershire
WR2 6LS
United Kingdom

Tel: 01905 640008
Fax: 01905 676464
www.jointmedica.co.uk

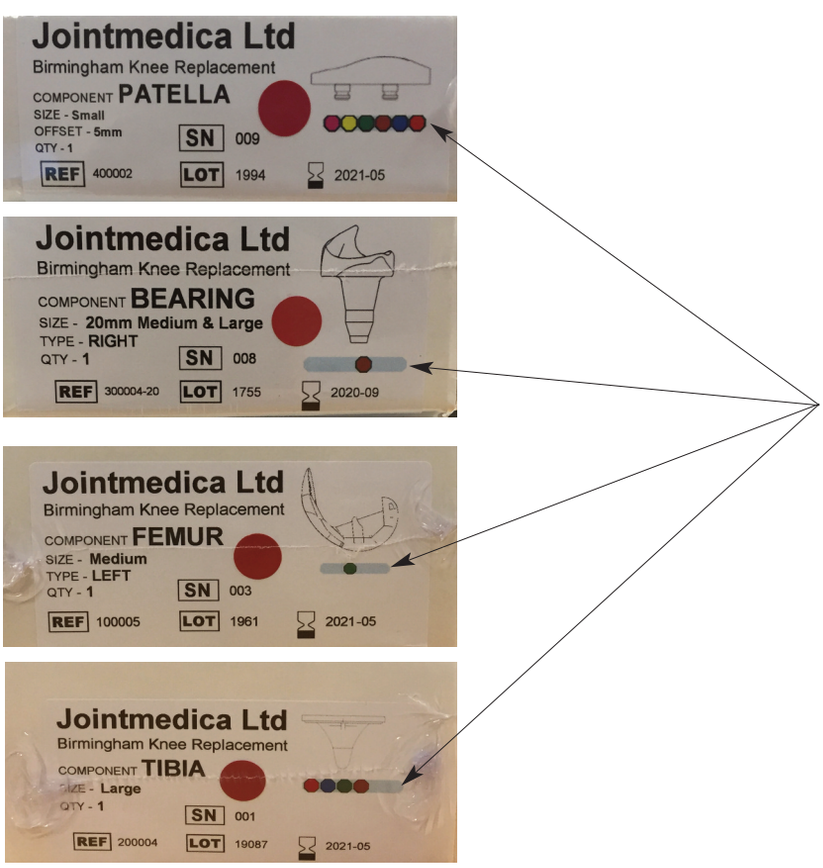
Instructions for use cat. No.904001
Issue 10 Nov. 2016

Instructions for Use

Implant Selection and Size-Matching Chart



Implant Box Colour Coding



Colour Coding is shown on the Implant Box Label

Please ensure colours are matched correctly

JointMedica Limited
Unit 3
Ball Mill Top Business Park
Main Road
Hallow
Worcestershire
WR2 6LS

Tel: 01905 640008
Fax: 01905 676464
www.jointmedica.co.uk

Cat. No. 905001
Issue 4 Jun. 2019

CE - for the Class I instruments.

CE 0088 - for the implants and Class IIa instruments.