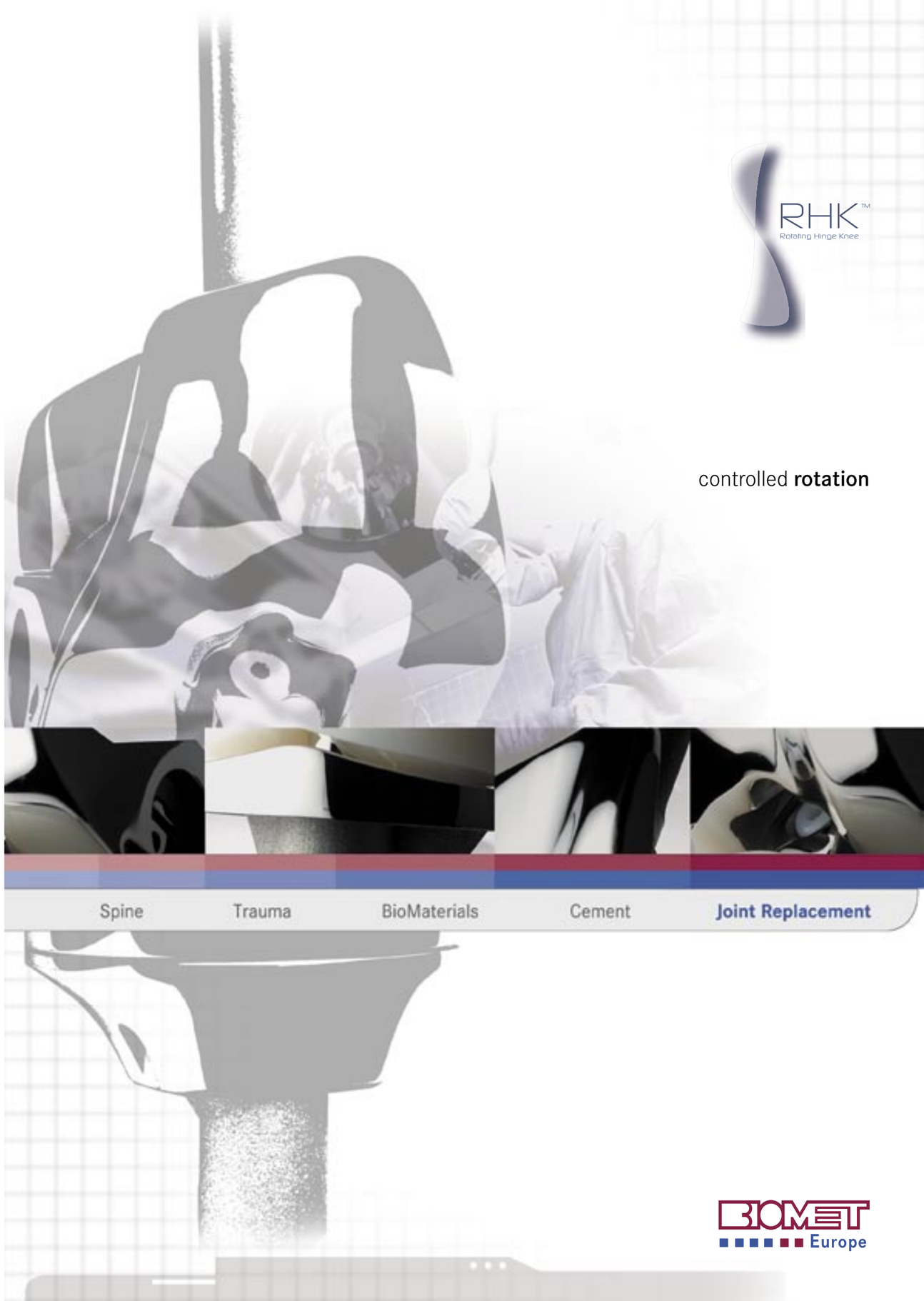
RHK™
Rotating Hinge Knee



controlled **rotation**

Spine Trauma BioMaterials Cement **Joint Replacement**

BIOMET Europe

FLK 128 04/04

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Foreword

The Rotating Hinge Knee (RHK™) was developed out of the requirement to reconstruct bony defects around the knee with a durable and mechanically efficient implant. The original indication was for joint reconstruction following resection of bone tumours. However, following experience with custom cases it was apparent that the indications could be expanded to include revision knee surgery, comminuted fractures around the knee, failed internal fixation and for primary knee replacement in those patients with connective tissue disorders. The RHK has been developed over nine years into a highly versatile implant, being available in both custom and modular forms.

One of the main advantages of the RHK, is the experience that Biomet has in the production of other implants within the 'AGC' family of knee replacements, the RHK representing one end of the spectrum of knee arthroplasties available. The main design features that the RHK offers above other similar implants are the efficient quadriceps lever arm, the minimal bone resection required and the large bearing area for the rotating mechanism. The RHK represents a significant step forward in the design of Rotating Hinge Knees. The implants inserted to date have all functioned well and there have been no reported failures up to 5 years. As appropriate to joint replacement, we would like to monitor the RHK's clinical success and would be grateful for your support in submitting the operative form for each case.

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Contents

Introduction

The RHK knee has been designed to treat the worst cases of instability or bone loss that the surgeon faces in Total Knee Arthroplasty. Consequently, the RHK is a versatile solution for cases where there has been a complete or nearly complete loss of Collateral Ligament function.

Indications

The indications include knee pain and dysfunction resulting from

- **severe osteolysis**
- **trauma**
- **oncology**
- **multiple revision arthroplasty**
- **salvage**
- **infection**
- **connective tissue disorders**

or any other condition where either significant bone loss or gross ligament dysfunction calls for total constraint from a class III or salvage knee.

Pre-Operative Planning

Successful revision arthroplasty requires thorough preoperative assessment. The cause or causes of failure need to be identified as far as clinically practicable pre-operatively and the operative management plan prepared.

A comprehensive range of templates for pre-operative planning are available and should be used to make a first choice of implants. Thus the fit of the implants can be visualised and also what options may be available intra-operatively.

Femoral Preparation

1. Initial preparation follows the removal of implants, any evidence of disease as appropriate, bone cement, osteophytes and any soft tissues in the operative field.

Enter the femoral canal with the pointed 9mm starter drill[1]. For the primary knee, this should be approximately 1 cm above the middle of intercondylar notch. Whether for primary or revision knee, the objective is to clear any metaphyseal/ epiphyseal bone, permitting the hand reamers access to the intramedullary canal.

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2. Use the T-Handle to ream, fully rotating the reamer to clear the femoral canal[2]. Insert up to the pre-planned level (marked on the shaft). For a short femoral stem, ream until the cutting flutes fully enter the intramedullary canal[3] and to the first mark on the shaft for the long femoral stem. For primaries, insert the reamer to allow for the bone to be removed from the distal femur. Do not let the reamer drift posteriorly as the implant is designed with an anterior stem position to aid the fit of long stems into the bowed femoral canal.

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3. After the 10mm reamer, insert progressively larger reamers (in 2mm steps) until the reamer starts to take bone off the intramedullary canal (this is the point at which cortical chatter is felt). For cementless stems, the reamer is the same diameter as the root of the stem, so the stem flutes bite into the cortex during insertion. This provides a very strong rotational interlock. For cemented stems, there should be a cement mantle of at least 1mm around the stem. Thus for a 12mm cemented stem, use the 14mm reamer or larger. When the size and

length has been chosen, it is often useful to tap the reamer into the canal about 1cm further to get a good stability and alignment (tapping too hard can cause the reamer to become stuck).

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4. It is possible at this point to use the femoral sizing templates to estimate the size of femur and what augments may be required. Notches on the anterior flange of the template indicate the position of the 10, 20 and 30 mm augments. Place each template on either the medial or lateral sides of the femur and line the handle up with the reamer shaft [4].

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Assemble the fixed valgus guide block and the distal resection adapter onto the reamer [5] through the left or right hole noting the anterior marking. As the distal condyle thickness of the RHK is 19mm, the distal resection guide should be set to 19mm for a primary knee. For a revision knee, estimate the amount of bone loss using the removed femoral component and any attached augments. Consider the joint line position and use augments as necessary to position it correctly. It is suggested that the joint line should be 10-20mm below the distal pole of the patella [A]. Enough bone should be resected to obtain good solid bony platform to support the implant. If a 10mm distal augment is required, use the 10mm slot in the guide. For the 20 augment, adjust the guide to add an additional 10mm and cut through the +10 cutting slot. For the 30mm augment, set the guide to 20mm axtra and use the +10 cutting slot in the femoral cutting block.

Fix the distal cutting block with three pins. Insert the proximal central pin first into appropriate left or right hole and then two pins through the angled distal holes which give the best stability.

Remove all the components except the cutting guide [6] to perform the distal cut [7].

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A Figgie et al. JBJS Vol 68-A, No. 7, SEPT, 1986

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To prepare the femoral contours, use the chamfer cutting block irrespective of selected augments [8]. If augments are being used, then the appropriate sized augment spacer [10, 20 or 30mm] should be screwed into the chamfer block to stabilise the block onto the distal femur. Reintroduce the reamer, pass the cutting block over the shaft of the reamer into the marked left or right hole. Using the handles as a rotational guide, set the required external rotation from the transepicondylar axis, Whiteside's line or if they still exist, the posterior condyles. Nail the block into place and use either locking bolt to lock onto the reamer, especially where bone quality or bone stock is poor [9]. The long headed nails may be located in either the angled medio-lateral holes, or the distal holes. Alternatively, they may be inserted very deeply through the larger holes near the posterior edge of the block. The distal holes have been used the appropriate nail must be removed in sequence to allow the saw blade to pass through each side.

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Option – On primary knees with good femoral bone stock, the femoral cutting block can be located with two pegs, similar to primary knee instrumentation. To drill the peg holes into the distal femur, use the optional intra-medullary drill guide. Slide it down the reamer, nail into position and use the stepped drills provided. The contour block accepts screw in pegs, which locate into these holes.

Make the anterior and posterior cuts in that order, before removing all instruments except the reamer.

Assemble the femoral frame with the intramedullary guide bush, noting correct orientation for the left or right leg and locking the bush into the frame with a long cross nail [10]. Where femoral augments are being used, screw in the trial spacers of 10, 20 or 30mm to the underside of the frame. The frame has the posterior chamfer cut built in to maximise stability, and there are a variety of nail holes to use when there is significant bone loss. It is recommended that two headless nails are inserted anteriorly and two headed nails distally. Once the frame is secure, remove the intramedullary guide and reamer.

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Where only one or neither femoral augments are being used, the femoral box needs to be cut. Pass the chisel through the anterior opening of the femoral frame underneath the guide pins. To avoid the risk of fracturing the posterior cortex, only insert about 4mm with the bevel on the distal side. Use an oscillating saw to cut down to the chisel along each side of the box and run posteriorly at the same level to obtain the correct depth of the box [11]. Impact the chisel all the way to the mechanical stop, being careful not to fracture the posterior cortex, especially in sclerotic bone. At the end of travel, the chisel is released from the guide pins and can be lifted out with the cut intercondylar bone [12].

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Place the femoral reamer guide into the femoral frame, noting left or right orientation [13]. Use a long cross nail to fix the guide into the femoral frame. Ream the femur with the square ended femoral reamer using the T-handle [14].

Initial femoral preparation is now complete. Remove all the instruments for trialling.

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Trial each femoral component to optimise cortical coverage before attaching stems and augments.

With the selected femoral trial component, attach the appropriate femoral trial augments with the driver [16]. It is advisable to trial the femoral component without the stem first and use a light hammer on the impactor to confirm that all cuts have been performed adequately. At this stage it is easy to trial different size femurs to maximise cortical coverage. Remove the femoral trial and attach the trial stem. Use the hex driver through the intercondylar notch of the femur to secure the captive nut onto the stem [17].

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Impact the assembled femoral component into the prepared femur. Note the anterior marking on the femoral impactor block [18].

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Tibial Preparation

Initial preparation of the tibia involves removal of all previously implanted components, diseased tissue and cement as for the femur.

An extra-medullary guide is provided, but it is highly recommended that intramedullary alignment is used as a matter of course, especially for cementless stems.

Use the pointed 9mm drill to gain access to the tibial intramedullary canal [1]. The entry point should be approximately 16mm behind the anterior border of a normal tibia and on the midline of the tibial plateau. Inserting the drill under power 50mm into the tibia should clear the cancellous bone of the epiphysis and metaphysis in a normal tibia. It is often useful to place a thumb & finger either side of the shaft to aim the drill

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Use the same reamers as for the femur and the T-handle to progressively ream larger until cortical bite is achieved [2]. Minimal reaming by hand is all that should be required. As in the femur, use the same size stem as the reamer for uncemented stems and at least one size down for cemented stems. The length of stem is indicated on the reamer. The two rings on the shaft indicate the depth for the short and long tibial stems respectively (marked for 80 and 120mm tibia). As in the femur, remove the T-handle and tap the reamer lightly to engage it firmly in the canal (caution: firm tapping will make the reamer very difficult to remove).

2

Assemble the intra-medullary tibial guide using either guide block and stylus [3,4]. Slide the assembly down the reamer and lock at the level indicated by the stylus. The driver can be used to lock the nut firmly. It is worthwhile sliding the angel wing through the slots to make sure the resections will cut at the right level, right to the back and give a good balance between creating a solid bone footprint and protecting the proximal fibula, collateral ligaments or patella insertion. Slide the tibial cutting assembly posteriorly to abut onto the tibia. Tighten large top and then the large side screw [5].

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Insert two headless nails with the quick release chuck through the lowest holes on the guide block. The reamer may be left in place if the bone quality is too poor to get adequate fixation with the quick release nails. In this case, saw around the reamer and finish the cut as necessary after removing the reamer and guide [6]. Each line of nail holes in the blocks are 2mm apart, allowing the block to be moved down in 2mm increments.

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Augment cuts can be made using the dedicated 10, 15 and 20mm slots on the three slotted guide block [3].

Replace the reamer and tap lightly home. Drop various tibial templates over the reamer until the best size to match both the position of the reamer and the size of the tibia is found [7]. Screw the augment spacer trials as necessary to the underside of the template (10, 15 or 20mm). Align the template correctly by attaching the tibial tower with the anterior screw and drop the intramedullary bush into the tower. The entire assembly can then be slid down the reamer to sit on the proximal tibia [8]. Confirm external rotation with the extramedullary rod through the modular handle attached to the front of the template. Align it with the second metatarsal before nailing the template into place with the long nails.

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Remove the reamer and intramedullary bush, leaving the template and tower in place. Use either the short tibial reamer for a modular tibia [9] or long reamer (both marked) for a monoblock tibia [10]. Use the T-Handle to manually ream until the reamer bottoms out on the mechanical stop.

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Remove the reamer and drive the fin punch through the tower until reaching the mechanical stop [11]. Use caution on very small tibias in case there is cortical impingement.

Assemble the chosen tibial component with the appropriate stem and augments as necessary[12]. Screw the chosen stem directly into the tibial component. Use the small Hex Driver to attach the tibial augments. Impact into the prepared tibia, paying particular attention to the alignment of the fins into the tibial plateau [13]. The tibial augments are tapered distally matching standard tibial geometry.

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Spacer Trialling

The size of the bearing is determined by the size of the tibial component. The thickness of the bearing is determined by soft tissue tension. The thickness of the bearing should not place undue tension on the soft tissues including neural vascular bundles. The knee should be able to flex and extend freely throughout the range of motion.

After impacting both the trial tibial and trial femur, insert the trial femoral bushes into the condyles from inside the intercondylar box. Drop the trial yoke into the trial tibia, putting the axle boss between the femoral condyles. After lining up the axel bore, pass the trial axle through the femur from either side and through the yoke. Trial bearings can be inserted in turn from the front until adeqaute stability is reached.

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Implant Assembly

For the femoral component and for modular trays, use the screw packaged with the femoral and tibial component to fix the stem in place. The femoral component has an orientation tag for the stem, whilst the stem for the tibia can be put in at any rotation. For uncemented stems of 16mm or greater diameter, there is a coronal slot in the tip to reduce stem stiffness and the possibility of shaft pain. Stems of 160mm are available with an anterior bow to match the femoral intramedullary geometry.
The screw supplied with the uncemented stems should be discarded in favour of the screw packaged with each component.

Insert the stems with the chosen rotation into each modular component. Seat the stem down fully by putting a clean swab over each end, and with the component resting on a stable surface, apply a sharp blow to the stem tip. Once properly seated, insert the screw with the driver and tighten firmly. The stems have a Spiralock© self locking thread to positively retain the screw.

Attach augments using the driver to screw each into place. The screws are supplied with each augment and no cement is required.

Implantation

It is usually most convenient to implant the femoral and tibial components separately as the hinge mechanism can be inserted very easily afterwards. Especially in tight knees, it is often easiest to implant the tibia first.

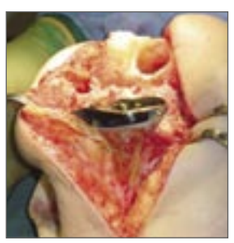
After impacting the femoral and tibial component, insert the tibial bush into the tibia, narrow end first. Fit the femoral bushes from inside the intercondylar box, the narrow ends first. Drop the appropriate yoke into the tibia, and fit the axle boss into the intercondylar notch.
The short yoke should be used for bearings from 12 to 16mm thick and the long yoke for 18 and 20mm thick bearings.

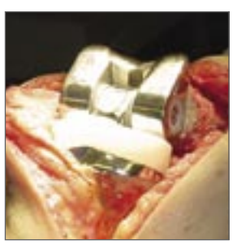
Slide the axle from either medial or lateral through the posterior condyles and yoke to connect the femur and tibia. The axle is positively locked into place using the polyethylene lock pin through the front of the yoke. Only insert the lock pin once the bearing thickness and yoke have been chosen. The pusher can be used to drive it home.

Once inserted, the pin is very difficult to remove.

A drill bit of the right size and spare lock pin are supplied should it be necessary to disassemble the knee.

If the bearing thickness could not be determined during trialling, then the implanted components are fully compatible with all the trials. However only use the trial yoke in the trial tibia to prevent scratching the tibial bush. A longer yoke is available for 18 and 20mm thick bearings to increase engagement. If the bearing thickness cannot be determined during trialling, then use the trial yoke for cementing. Always insert the locking pin last, after confirming all the components are correct and inserted. When using the trial axle, do not insert the implant locking pin.





Cement Spacers

A range of cement spacers for both knees and hips for performing two stage revisions are available. Conventional manual cement spacers simply maintain the gap between the femur and the tibia, normally fixed in extension. Biomet Cement Spacer Moulds are two piece cement spacers, similar to metal impants in shape.

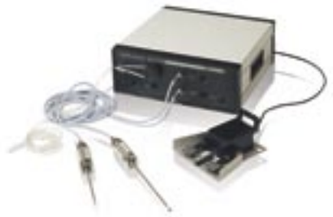
The spacer moulds permit joint flexion; thereby reducing the risk of stiffening during the six to eight week normally required to resolve an active periprosthetic infection. The medical grade silicone spacers can be filled by cement gun for the femur, while the tibial spacer can be easily filled by pouring cement to the desired thickness marked on the spacer. Once cured, the antibiotic loaded mould is removed from the silicone and implanted into the joint space.

Cataloge Number	Femoral Mould size	Recommended Cement Mixes per Mould
432 160	60mm	2
432 165	65mm	2
432 170	70mm	2
432 175	75mm	2
Tibial Mould size		
433 165	65mm	2
433 170	70mm	2
433 175	75mm	2
433 180	80mm	2

Copal®
Dual antibiotic bone cement

Copal is a broad spectrum, high viscosity antibacterial cement designed specifically for use in revision arthroplasty and for the treatment of infection. Based on Refobacin-Palocos R, the combination of gentamicin and clindamycin delivered with higher antibiotic concentration and longer lasting release make Copal useful for either single or two stage revisions. The combination of gentamicin and clindamycin are known to have an antibacterial effect on over 90% of the bacteria common in infected arthroplasty (Forster et al, 1988). Copal is fully compatible with Biomet-Merck cement spacer moulds and modern cementing technique, making a very useful clinical option for both single and two stage revision.

ULTRA-DRIVE™



Ultra-Drive™ is designed to rapidly loosen cement and components without risking damage to bone or soft tissues. The high frequency vibration temporarily liquifies the cement whilst any contact with bone is instantly audible, allowing the surgeon to limit damage. Distal cement plugs are quickly and easily removed, normally without the need to resort to cortical windows and reducing the risk of thinning or perforating bone.

The result is reduced operative time incurring decreased blood loss, risk of bone loss tourniquet and anaesthetic time.

32-348058 Revision Staple

Particularly useful for revision procedures in tight knees or damaged patella tendon insertions. The revision staple reinforces the patella tendon, reducing the risk of avulsion.

800-003-00 Manual Revision Instruments

A complete range of manual instruments, specifically designed for implant removal, are available on request. The instruments feature high impact, ergonomically designed handles for minimal hand fatigue and precise application. A set of modular flexible osteotomes can also be included.

Options

The Gravitational Platelet System (GPS™) is designed to use the body's natural healing processes by taking platelet concentrate systems to a new level of performance and simplicity.

GPS™ uses a small volume of patient blood supplied at the point of care to provide a consistently high quality platelet concentrate. At over 85% platelet recovery and with an automatic separation plug that positively separates the components, the GPS™ is easy to use and outperforms the leading systems on the market. Platelets are quickly separated using a single spin system whilst all the required disposables are supplied in one kit. The healing growth factors carried by the patient's platelets can then be applied with a non-contact spray system.

31mm	11-1500861
34mm	11-150 862
37mm	11-150 863

Construct™

The Construct™ Suture Patella is designed to give the surgeon a wide range of options to assist reconstruction of patellas with poor stability, low bone stock, or after patellectomy, patella tendon or quadriceps tendon rupture. The anchoring sutures can also be used for positive alignment and improved tracking, or to alter patella baja or alta. If sutures are not required, Construct™ can be implanted without sutures and cemented like a standard patella.

Resurfacing Femoral Components

Small Right	154975
Standard Right	154976
Small Left	154978
Standard Left	154979

Tibial Components

63 Modular Tibial Tray	154987
67 Modular Tibial Tray	154988
71 Modular Tibial Tray	154989
75 Modular Tibial Tray	154990
79 Modular Tibial Tray	154991

63 Stemmed Tibial Tray	154993
67 Stemmed Tibial Tray	154994
71 Stemmed Tibial Tray	154995

Connectors

Long Yoke (18, 20 bearings)	154999
Short Yoke (12, 14, 16 bearings)	154997
Axle	154998
Locking Pin	154972
Tibial Bush	154973
Femoral Bush	154974

Bearing

63x12 RHK Tibial Bearing	159430
63x14 RHK Tibial Bearing	159431
63x16 RHK Tibial Bearing	159432
63x18 RHK Tibial Bearing	159433
63x20 RHK Tibial Bearing	159434
71x12 RHK Tibial Bearing	159435
71x14 RHK Tibial Bearing	159436
71x16 RHK Tibial Bearing	159437
71x18 RHK Tibial Bearing	159438
71x20 RHK Tibial Bearing	159439

Uncemented Stems

80 x 10 RHK Uncemented Stem	141 610
80 x 12 RHK Uncemented Stem	141 612
80 x 14 RHK Uncemented Stem	141 614
80 x 16 RHK Uncemented Stem	141 616
80 x 18 RHK Uncemented Stem	141 618
80 x 20 RHK Uncemented Stem	141 620
80 x 22 RHK Uncemented Stem	141 622
80 x 24 RHK Uncemented Stem	141 624
120 x 12 RHK Uncemented Stem	141 652
120 x 14 RHK Uncemented Stem	141 654
120 x 16 RHK Uncemented Stem	141 655
120 x 18 RHK Uncemented Stem	141 656
120 x 20 RHK Uncemented Stem	141 657
120 x 22 RHK Uncemented Stem	141 658

Cemented Stems

RHK 10x80 RHK Cemented Stem	159403
RHK 12x80 RHK Cemented Stem	159405
RHK 14x80 RHK Cemented Stem	159407
RHK 16x80 RHK Cemented Stem	159409
RHK 10x120 RHK Cemented Stem	159414
RHK 12x120 RHK Cemented Stem	159416
RHK 14x120 RHK Cemented Stem	159418
RHK 16x120 RHK Cemented Stem	159420

Implant Listing

Femoral Augments

Sml 10 Fem Augment LL	159447
Sml 10 Fem Augment LM	159448
Sml 10 Fem Augment RL	159449
Sml 10 Fem Augment RM	159450
Sml 20 Fem Augment LL	159451
Sml 20 Fem Augment LM	159452
Sml 20 Fem Augment RM	159453
Sml 20 Fem Augment RL	159454
Sml 30 Fem Augment LL	159455
Sml 30 Fem Augment LM	159456
Sml 30 Fem Augment RL	159457
Sml 30 Fem Augment RM	159458
Std 10 Fem Augment LL	159460
Std 10 Fem Augment LM	159461
Std 10 Fem Augment RL	159462
Std 10 Fem Augment RM	159463
Std 20 Fem Augment LL	159464
Std 20 Fem Augment LM	159465
Std 20 Fem Augment RL	159466
Std 20 Fem Augment RM	159467
Std 30 Fem Augment LL	159468
Std 30 Fem Augment LM	159469
Std 30 Fem Augment RL	159470
Std 30 Fem Augment RM	159471

Segmental Bone Replacement

Modular Segmental components are available from the Customs Department at Biomet UK Ltd to suit the RHK™, both rapidly and cost effectively. The team has many years of combined experience, with a wide range of successful custom solutions from clavicular replacement, to growing prostheses to total femoral replacements. When you need larger bone replacement that only segmental components can deliver, the Customs Department can supply these at short notice, designed and built using all the experience from the many successful implantations since 1998.

Tibial Augments

63x10 Tibial Augment RM/LL	159473
63x10 Tibial Augment RL/LM	159474
63x15 Tibial Augment RM/LL	159475
63x15 Tibial Augment RL/LM	159476
63x20 Tibial Augment	159477
67x10 Tibial Augment RM/LL	159478
67x10 Tibial Augment RL/LM	159479
67x15 Tibial Augment RM/LL	159480
67x15 Tibial Augment RL/LM	159481
67x20 Tibial Augment	159482
71x10 Tibial Augment RM/LL	159483
71x10 Tibial Augment RL/LM	159484
71x15 Tibial Augment RM/LL	159485
71x15 Tibial Augment RL/LM	159486
71x20 Tibial Augment	159487
75x10 Tibial Augment RM/LL	159488
75x10 Tibial Augment RL/LM	159489
75x15 Tibial Augment RM/LL	159490
75x15 Tibial Augment RL/LM	159491
75x20 Tibial Augment	159492
79x10 Tibial Augment RM/LL	159493
79x10 Tibial Augment RL/LM	159494
79x15 Tibial Augment RM/LL	159495
79x15 Tibial Augment RL/LM	159496
79x20 Tibial Augment	159497

Patella

Small (31 mm)	11-150820
Medium (34 mm)	11-150822
Large (37 mm)	1-150824

Instruments

RHK Instrument Set	32-421440

Does not include patella instruments

X-Ray Templates

RHK X-Ray Templates - 110% Magnification
RHK X-Ray Templates - 115% Magnification
RHK X-Ray Templates - 120% Magnification

Notes

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