





# BIRMINGHAM HIP<sup>◇</sup>

## Resurfacing System

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### Nota Bene

The technique description herein is made available to the healthcare professional. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

# Indications for use

The BIRMINGHAM HIP<sup>®</sup> Resurfacing (BHR<sup>®</sup>) System is a single use device intended for hybrid fixation: cemented femoral head component and cementless acetabular component.

The BHR System is intended for use in patients requiring primary hip resurfacing arthroplasty due to:

- Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia/DDH, or
- Inflammatory arthritis such as rheumatoid arthritis.

The BHR System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision.

## Contraindications

- Patients who are female
- Patients with infection or sepsis
- Patients who are skeletally immature
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Patients with bone stock inadequate to support the device including:
  - Patients with severe osteopenia or patients with a family history of severe osteoporosis or severe osteopenia.
  - Patients with osteonecrosis or avascular necrosis (AVN) with >50% involvement of the femoral head (regardless of FICAT Grade).
  - Patients with multiple cysts of the femoral head (>1cm).
  - Note: In cases of questionable bone stock, a DEXA scan may be necessary to assess bone stock status.
- Patients with known moderate to severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who are severely overweight
- Patients with known or suspected metal sensitivity (e.g., jewelry)

## Warnings and precautions

- Patients who, from plain radiograph pre-operative templating, appear to require 48mm femoral heads should not be considered as candidates for BHR implantation. Patients requiring a 48mm femoral head size are at a moderately elevated risk of requiring revision surgery earlier than expected. While Smith & Nephew concluded that the increased risk associated with this head size does not outweigh the potential benefit to the patient in the specific circumstance of intra-operative downsizing from a pre-operatively templated 50mm to a measurement of 48mm at the time of surgery, surgeons should use their best medical judgment to consider this information relative to the patient's overall medical history and prognosis in determining its appropriateness as a surgical treatment
- Patients on medications (such as high-dose or chronic aminoglycoside treatment) or with co-morbidities (such as diabetes) that increase the risk of future, significant renal impairment should be advised of the possibility of increase in systemic metal ion concentration. Preoperative and postoperative monitoring of renal function (such creatinine, GFR, BUN) will be necessary for these patients.
- Only physicians who have received appropriate training and are familiar with the implant components, instruments, procedure, clinical applications, adverse events, and risks associated with the BHR System should use this device. Contact Smith & Nephew Orthopaedics Ltd. for the surgical technique manual and procedural training protocol.
- Based on literature reports together with the manufacturer's post-market data, the following were identified as risk factors for early revision:
  - Patients who receive a 48mm femoral head;
  - Patients who receive a device which is incorrectly positioned;
  - Patients who have a diagnosis of avascular necrosis;
  - Patients who have congenital dysplasia; and
  - Patients who are obese

The more risk factors the patient has, the greater the risk of procedure failure requiring a revision of the hip.

**For additional information on the use of the BHR device, see the Instructions for Use printed at the end of this surgical technique.**

## The surgical approach

The BIRMINGHAM HIP<sup>®</sup> Resurfacing device may be implanted through all normal surgical approaches.

The posterior approach is described in this operative technique.

# Preoperative planning

## Templating

BHR° template sets (Figure 1) are used to determine component size and correct implant positioning. The position of the femoral component is a most important pre-operative consideration. Varus positioning must be avoided and slight valgus is recommended (Figure 2).

To achieve optimal femoral component positioning, place the appropriate BHR template onto the X-ray. Once happy with the size chosen the medial head-neck-junction may be identified to set up the correct template positioning. This is aided by using the cut out section on the template which allows implant position markings to be made with the template in situ.

With the head-neck-junction identified the template is rotated around this point until desired valgus position is achieved with the implant's centre line. One limiting factor for implant positioning is the risk of femoral neck notching. This may be avoided at the templating stage by confirming there is no contact between the superior aspect of the femur and the template.

Once satisfied with the template positioning, the X-ray may be marked on the lateral cortex of the femur using the appropriate cut-out section. The marked position shows the insertion point for the lateral pin used with the standard Head-Centre-Alignment-Jig.

The distance from the pin insertion point on the lateral femoral cortex to the tip of the greater trochanter is measured with the ruler found on the edge of each template. This measurement is translated intraoperatively onto the patient's femur to achieve optimal pin placement.

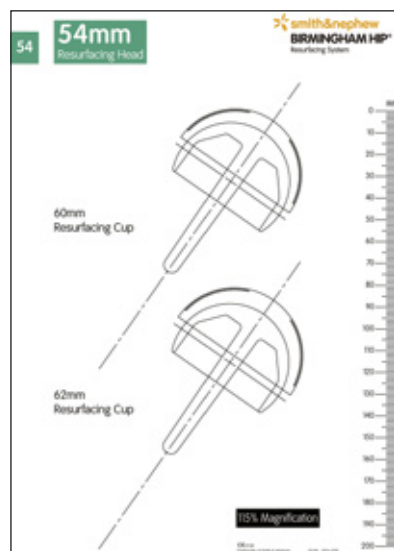


Figure 1

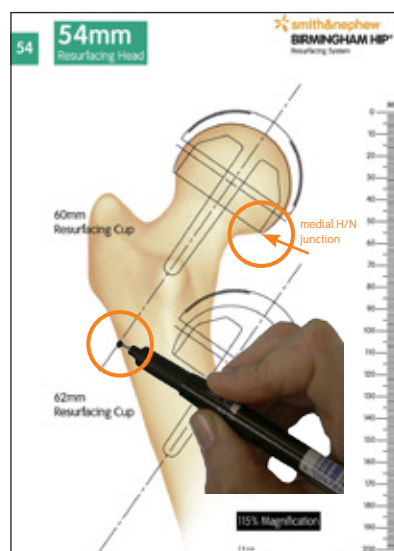


Figure 2

# Intraoperative templating

An assessment is made of the femoral neck diameter using the head/neck template. This provides vital information as to minimum head component size that can be safely used and also the minimum acetabular size that can be utilised. If significant osteophyte formation is present on the femoral neck then this should be removed with rongeurs before definitive assessment of femoral neck diameter is made (Figure 3,4).

**NOTE: Care should be taken to avoid damage to the soft tissue and blood supply during osteophyte removal.**

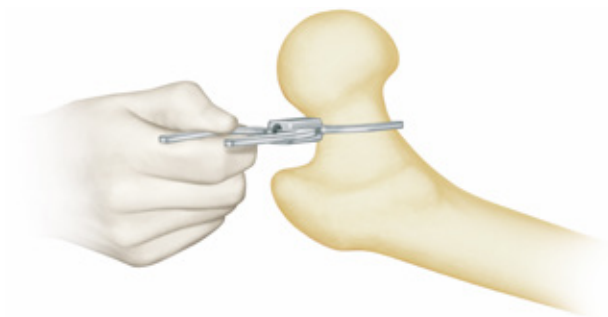


Figure 3

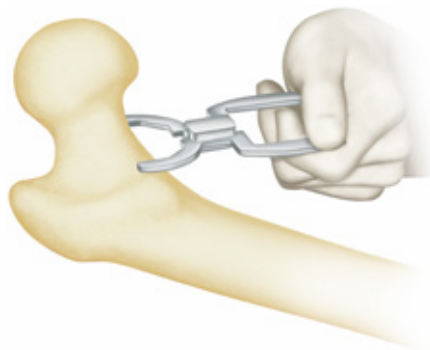


Figure 4

# Acetabular preparation

If the anteroinferior capsule is tight an antero-inferior radial capsulotomy is made in line with the psoas tendon. A Hohmann retractor is placed inferior to the radiographic teardrop. The acetabular labrum, transverse ligament and ligamentum teres are excised revealing an unencumbered view of the complete acetabulum and a view of the true floor of the acetabulum. Sequential reaming with hemispherical acetabular reamers is then performed and in normal consistency bone, reaming proceeds to 2 mm less than the definitive acetabular component to be inserted (Figure 5).

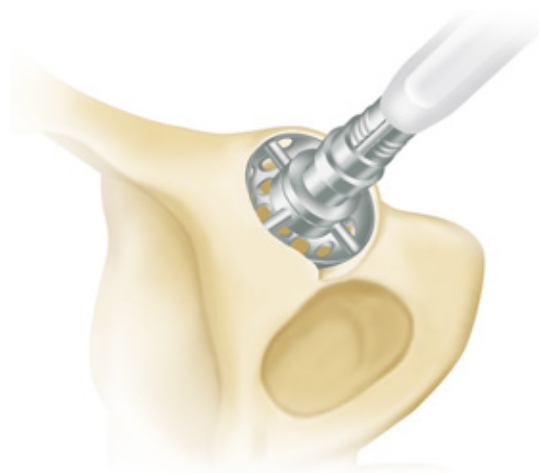


Figure 5

In large patients with soft cancellous bone 3 mm under-reaming is recommended. In small patients with sclerotic acetabulae 1 mm of under-reaming is recommended.

The cup trial may be used to determine correct implant positioning. If in doubt, medical tweezers can be used to identify optimal seating of the cup. The trial is 1 mm smaller than the definitive component size (Figure 6).

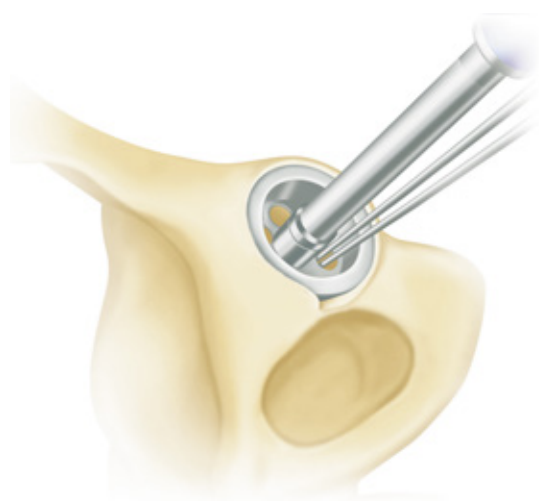


Figure 6

Posteroinferior and anteroinferior osteophytes are excised to allow unobstructed cup insertion. Please note that some designs of acetabular reamers do not have teeth at the periphery and the acetabulum may be unreamed at its periphery making cup insertion difficult (Figure 7).

It is recommended to leave a rim of osteophyte to prevent Psoas impingement on the wall of the acetabular component, avoiding post-operative groin pain.

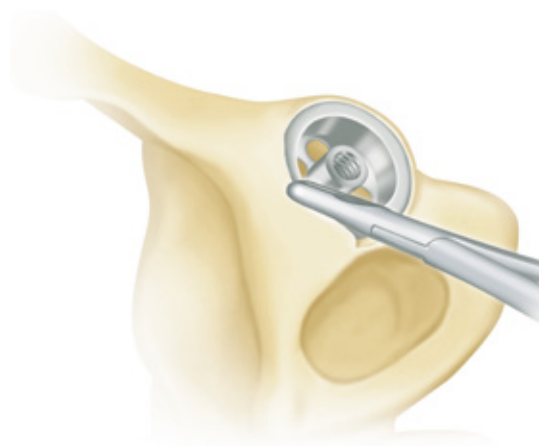


Figure 7

## High Performance Cup Introducer Inspection Procedure

The following instructions should be followed to maintain the performance of the BHR<sup>®</sup> Cup Introducer:

- All instruments should be inspected before use. Any instrument found with a loose or absent locking screw should be returned to Smith & Nephew for refurbishment. It is particularly important that a thread locking mechanism is used to secure the screws otherwise this problem may recur.
- There should be no excessive free play in the cable tensioning mechanism.



# Acetabular preparation

The desired size of acetabular component is mounted on the acetabular introducer and offered up to the acetabular rim. The acetabular cup is rotated so that its anti-rotation splines are adjacent to the ischium and pubis. The acetabular component is then fully impacted with 15-20° of anteversion and 40-45° inclination angle (Figure 8).

The acetabular introducer is removed and the polyethylene impactor cap is retracted at this stage to check that the acetabular component is correctly inserted. Adjustment of the cup position can be made by re-attaching the acetabular introducer. Cup removal is facilitated by the use of the slide hammer extractor attached to the acetabular introducer.

When it is certain that the component is correctly inserted, the cup introducer cables are cut and the cables and the polyethylene impactor cap removed (Figure 9). If the cup must be removed after the cables have been cut then separate cables and extractor assembly are available (code 900201&2). Any protruding osteophytes at the acetabular edge are removed with rongeurs. The femoral head is then reduced into the newly inserted acetabular component.

## \* Cautionary statement

*DO NOT over tighten the acetabular component on the introducer. Over tightening and excessive wire tension may cause wire breakage.*

## Acetabular Cup Introducer Wire Removal Procedure

The following instructions should be followed to minimise the risk of separating the plastic coating when removing the introducer wire.

- Use appropriate wire cutters, in good condition, for the cutting task.
- Minimise the number of wormholes the wire is pulled through (multiple cuts).
- Avoid acute angles between the wire and the cup face during withdrawal.
- If the force required to remove the introducer wire is excessive, remove the wire by pulling it in the opposite direction.
- Check that the plastic coating is still present on the wires following the wires removal.



Figure 8

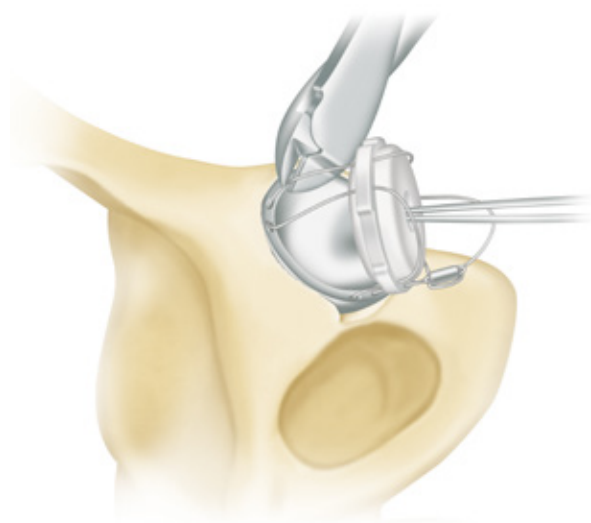


Figure 9

# Curved Cup Introducer

These instructions provide important information regarding assembly and wiring for use of the BHR<sup>®</sup> Curved Cup Introducer.

**NOTE:** This Curved Cup Introducer is for use with BHR Resurfacing cups only. It is advised that when using Dysplasia cups the Standard Straight Introducer should be used.



# Acetabular Cup wiring instruction

The following is the recommended method of attaching the Curved Cup Introducer to the acetabular component.

To ensure correct component fixation, please note that the wire loops are specified as wire loops 1, 2, and 3.

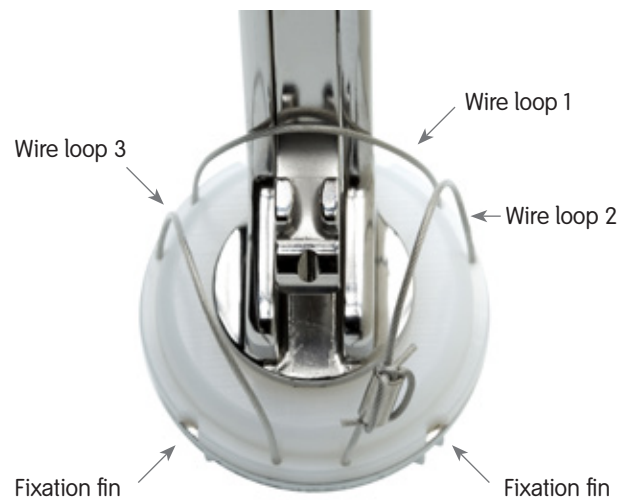


Figure 1

## Step 1

The acetabular component is placed over the threaded spigot on the face plate of the introducer, with the introducer passing through wire loop 1.

To ensure correct alignment, check that the fixation fins of the acetabular component are positioned either side of the device (Figure 1, 2).



Figure 2

## Step 2

Wire number 2 is then looped over the wire grip (Figure 3).

**Note: retracting the wire grip a small way, using the thumb wheel, will apply some tension to the wires and may aid the assembly.**



Figure 3

# Acetabular Cup wiring instruction

## Step 3

As in Step 2, now loop wire 3 over the wire grip (Figure 4).



Figure 4

## Step 4

With the two opposing wire loops (2&3) positioned through the wire grip now capture both wires by passing wire loop 1 over the top (Figure 5).



Figure 5

## Step 5

When satisfied that the cup wires are suitably positioned, secure the device by tightening the thumb wheel to a satisfactory tension (Figure 6).



Figure 6

# X-Bar

X-Bar (Figure 7)



Figure 7

The X-Bar is attached to the curved Cup Introducer. (Figure 8)



Figure 8

With the patient positioned correctly align the impactor so that the appropriate bar on the guide, left or right, is parallel to the longitudinal axis of the patient while the vertical bar is perpendicular to the floor. This will provide approximately 40-45° of abduction and 15-20° of anteversion. (Figure 9)

## Surgical Tip

- Target acetabular component orientation for optimal bearing function;  
40-45° of abduction  
15-20° of anteversion  
<45° combined stem/cup anteversion

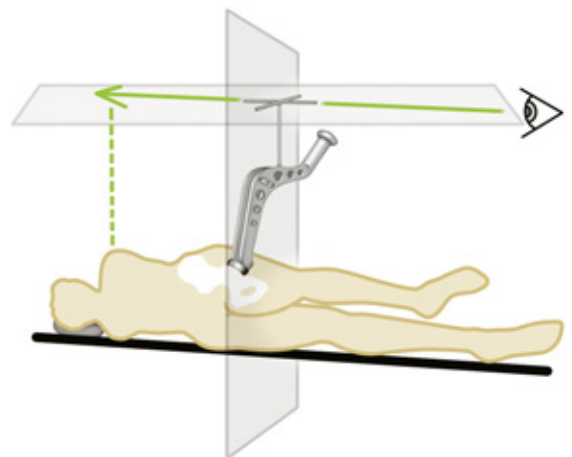


Figure 9

# Femoral preparation

The desired position of the femoral alignment pin will be known from the preoperative templating. Identify the tip of the greater trochanter through the tissues with a spinal needle.

A ruler is used to measure the desired distance down from the tip of the greater trochanter (Figure 1) and the alignment pin is inserted through the vastus lateralis fibres.

The front and back of the femoral shaft are felt and pin insertion is then started in a transverse direction into the mid-lateral cortex (Figure 2).



Figure 1



Figure 2

## Femoral preparation

After the outer cortex is breached the drill is angulated so that the alignment pin is directed towards the femoral head (Figure 3).

The alignment pin is left protruding 5 mm above the outer fibres of vastus lateralis.

**NOTE:** It is recommended that “Pin in Femur” is placed on the nurse’s swab count board.



Figure 3

## Using the McMinn Alignment Guide

The appropriate head implant size is set up on the head centre stylus. The alignment guide (Figure 4) is hooked onto the alignment pin and the leg fully internally rotated to deliver the femoral head into the centre of the wound.

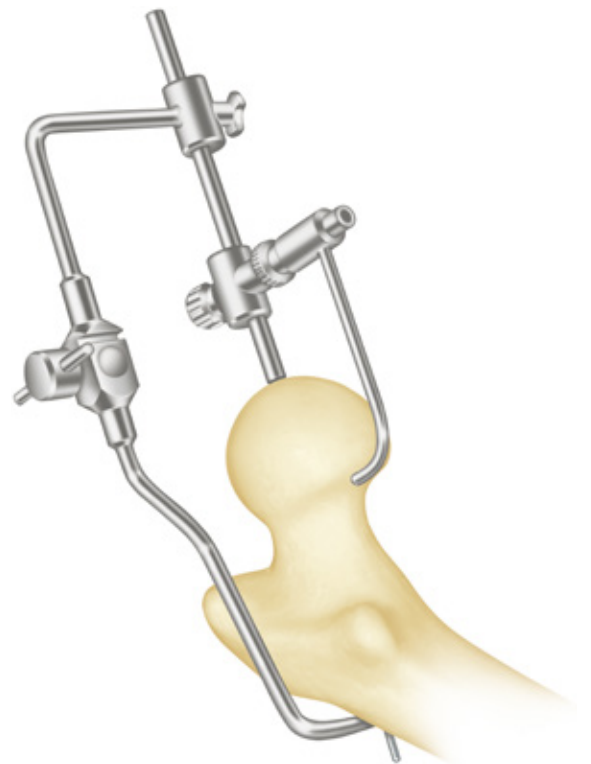


Figure 4

# Femoral preparation

The adjustable joint in the long arm of the alignment guide is set so that the guide wire will be directed down the mid-lateral axis of the femoral neck (Figure 5a). Bisect the neck with forceps to aid visualisation (Not illustrated).

Next the proximal portion of the guide is moved on the femoral head to allow the stylus to be passed around the femoral neck, having first been set to the desired femoral component size (Figure 5b, 5c).

When the stylus can be passed around the femoral neck at an equal distance, then the central cannulated rod is locked into position by impacting the teeth on this rod into the femoral head. Thus the whole assembly is stabilised. Fine-tuning of this position can then occur.

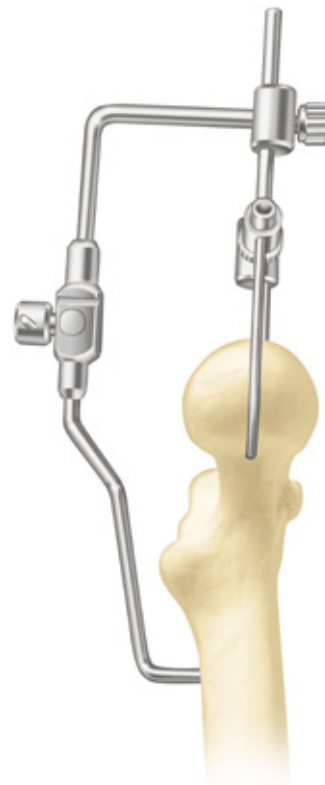


Figure 5a

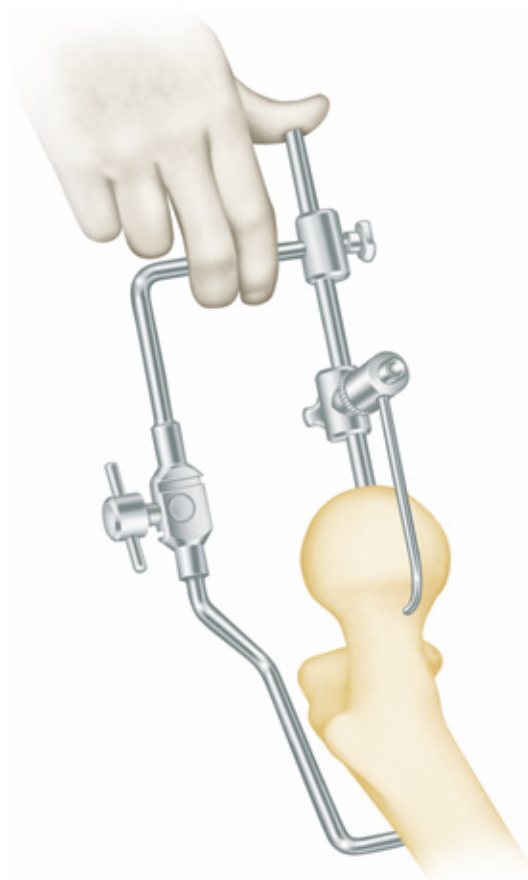


Figure 5b

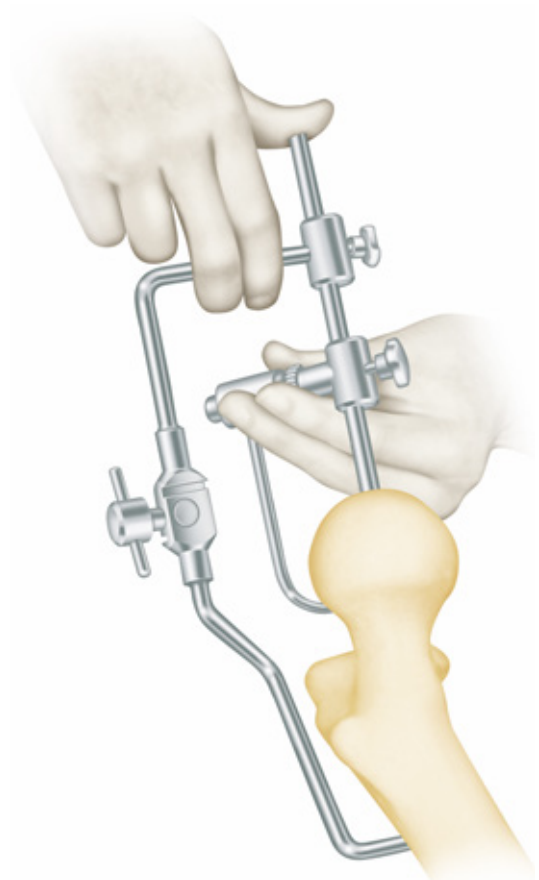


Figure 5c



# Short Arm Alignment Jig technique

## Templating

BHR<sup>o</sup> template sets are used to determine component size and correct implant positioning. The position of the femoral component is a most important preoperative consideration. Varus positioning must be avoided and slight valgus is recommended.

To achieve optimal femoral component positioning, place the appropriate BHR template onto the x-ray. Once satisfied with the size chosen the medial head/neck junction may be identified to set up the correct template positioning. This is aided by using the cut out section on the template which allows implant position markings to be made with the template in situ.

With the head/neck junction identified the template is rotated around this point until desired valgus position is achieved with the implant's centre line. One limiting factor for implant positioning is the risk of femoral neck notching. This may be avoided at the templating stage by confirming there is no contact between the superior aspect of the femoral neck and the template.

When the desired template position has been achieved, the distance from the tip of the lesser trochanter to the centre line of the implant template is measured. The long axis of the ruler template (Figure 6) is overlaid with the centre line of the implant template to identify the pin insertion point on the intertrochanteric crest. This measurement is translated intraoperatively onto the patient's femur using the measuring guide (Figure 7) to achieve optimal pin, Jig and ultimately femoral implant positioning. The pin insertion point may be marked using electrocautery or a medical needle to ensure optimal pin, jig and femoral positioning.

**NOTE: To achieve correct measurement from the tip of the lower trochanter to the pin insertion point, the patient's leg must not be externally rotated while taking the x-ray in supine position of the pelvis.**

**X-ray magnification must be taken into account during this preparation.**

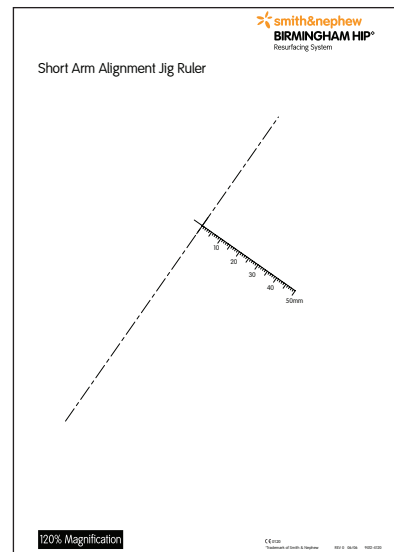


Figure 6- Short Arm Alignment Jig Ruler  
IMAGE NOT TO SCALE



Figure 7 - Measuring Guide

# Short Arm Alignment Jig

The measuring guide is placed on the tip of the lesser trochanter translating the preoperative measurement on to the intertrochanteric crest. The alignment pin insertion point can now be marked (Figure 8).

Using the marked insertion point on the intertrochanteric crest, the assembled jig is fixed to the femur by inserting the collared alignment pin through the hole in the distal slot of the alignment arm (Figure 9).

**NOTE: Care should be taken to use the correct collared alignment pin as this differs from the item used with the traditional long arm jig.**

The alignment jig can now be used to correctly position the long guide wire and ultimately achieve correct implant positioning (Figure 10).

The operation of the short arm jig remains consistent with the traditional McMinn alignment jig as described earlier in this surgical technique.

On correct positioning of the long guide wire the alignment guide assembly is released from the femur by first removing the collared pin.



Figure 8

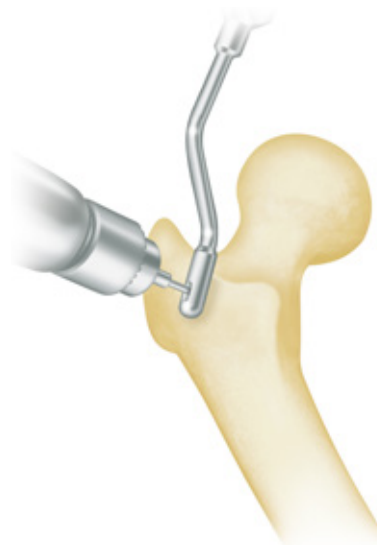


Figure 9



Figure 10

# Short Arm Alignment Jig

A guide wire is inserted when the desired position of the alignment guide has been achieved (Figure 11).

The central rod is removed and the guide assembly completely removed.

**NOTE: Guide wires are intended for single use only**

The stylus is re-inserted on the guide wire and a final check made to ensure that the stylus passes comfortably around the femoral neck (Figure 12).

**NOTE: A re-drill guide is available for the correction of minor alignment errors (Not illustrated).**

Secondly, a check is made to ensure that when the sleeve cut is made some peripheral femoral head support exists. This is not only important with respect to support for the implant, but is very important with respect to the pressurisation of cement. Care must be taken in cases of slipped epiphysis, or in pistol-grip deformity where the femoral head is not symmetrically located on the femoral neck.

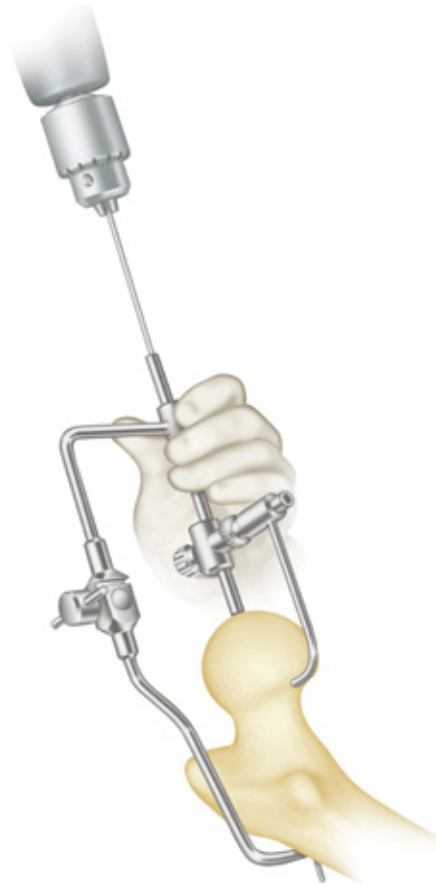


Figure 11

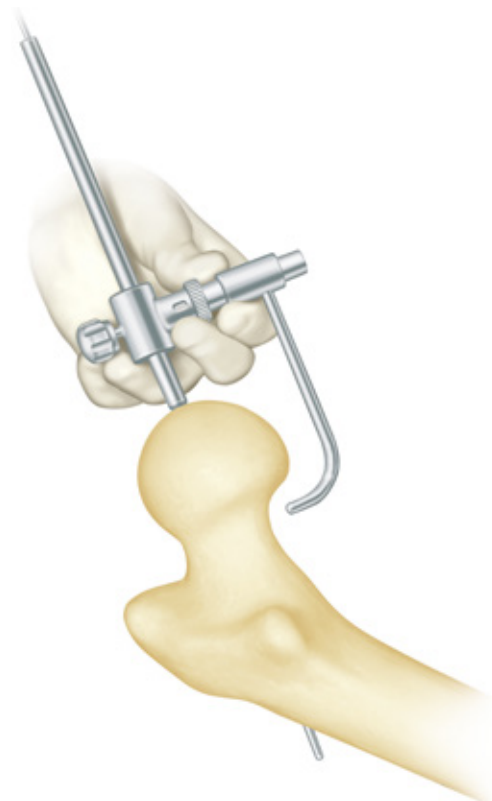


Figure 12

# Short Arm Alignment Jig

When the desired position of the guide wire has been achieved then the guide wire is overdrilled to the appropriate depth for the implant being inserted (Figure 13).

At this stage a hole is drilled and the vent is inserted into the lesser trochanter and connected to the second suction device (not illustrated).

The guide wire is removed and the guide rod inserted (Figure 14).

The most stability is achieved when the thicker lower aspect of the guide rod is placed flush with the bone (Figure 15).

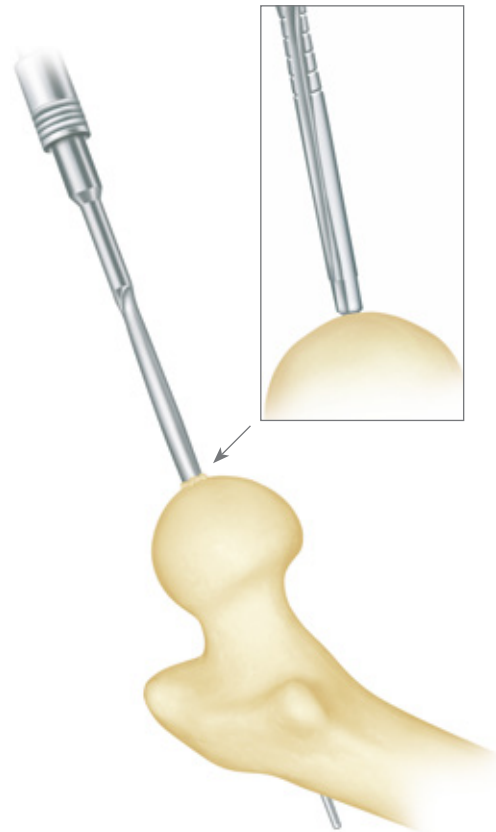


Figure 13



Figure 14

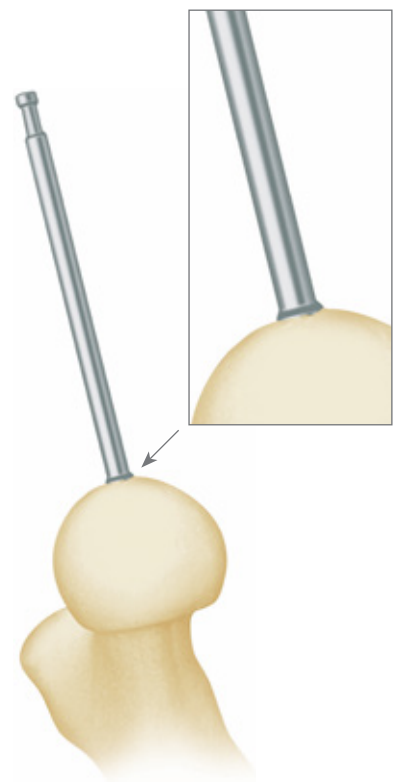


Figure 15

# Using the Sleeve Cutter Stop

The BIRMINGHAM HIP® Resurfacing (BHR®) Sleeve Cutter Stop was developed to reduce the risk of 'shoot through' and therefore femoral neck notching while preparing the femoral head.

This is achieved by providing a physical method of controlling the distance the sleeve cutter can travel when preparing the femoral head. The sleeve cutter stop stylus allows the surgeon to visualise the sleeve cutting diameter and depth on the patient's femoral neck before performing the sleeve cut.

The sleeve cutter stop stylus is used over the guide rod which has been inserted into the pre-drilled femoral head.

The appropriate head implant size and therefore sleeve cutter is set up on the sleeve cutter stop stylus. This is done in two ways; the first is to set the size using the thumb wheel this allows the chosen size to be read through the stylus window (Figure 16).

Secondly the stylus arm is set by moving it up or down within the body of the stylus until the correct size is shown on the scale along the top side of the stylus body (Figure 17).

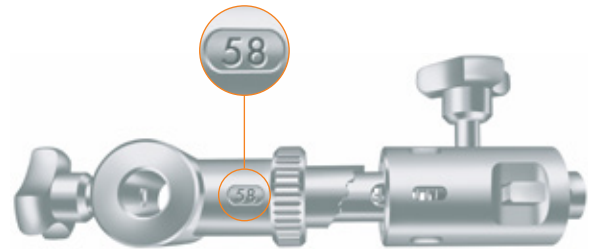


Figure 16

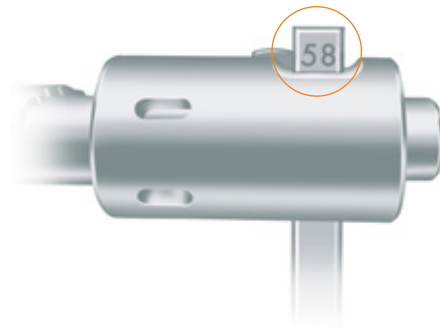


Figure 17

# Using the Sleeve Cutter Stop

The sleeve cutter stop stylus is placed on the guide bar. The stylus arm is passed over the femoral head.

It is the superior aspect of the femoral neck which is most prone to notching on 'shoot through' therefore this should be the starting point for positioning the tip of the stylus arm (Figure 18).

The positioning of the tip of the stylus denotes the depth the sleeve cutter will cut to (Figure 19.)

The tip of the stylus arm should be in contact with the femoral head but remain in clearance of the femoral neck.

The thumb screw is then tightened against the guide bar to set the chosen depth.

The stylus should now be passed around the femoral neck to confirm the chosen depth is accurate. (Figure 20 & 21)

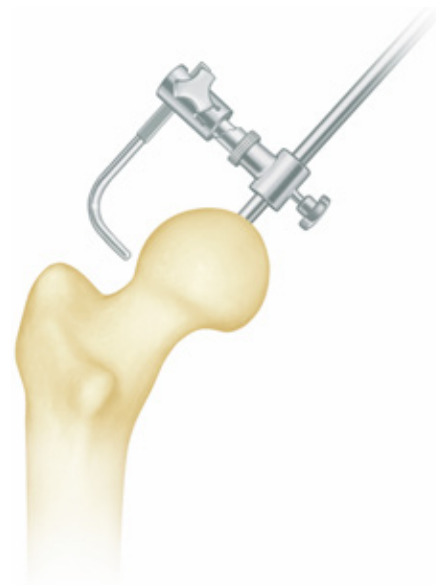


Figure 18

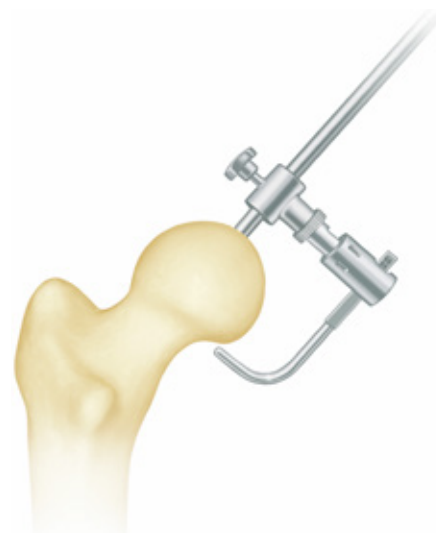


Figure 19

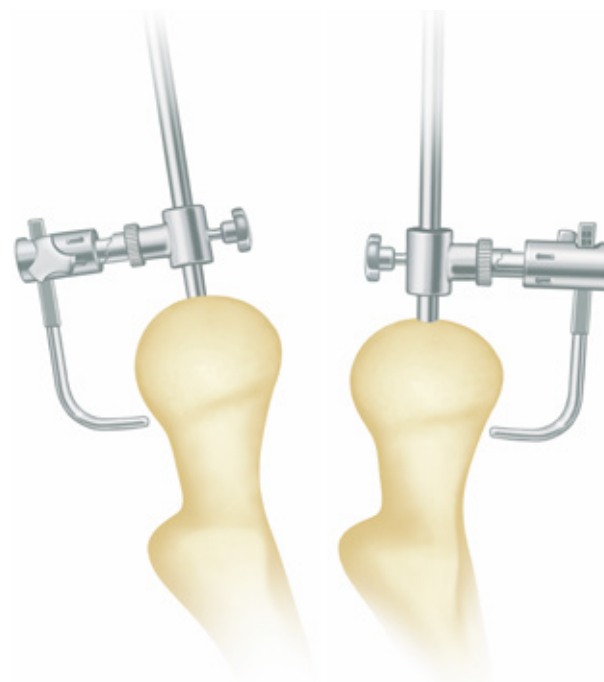


Figure 20 & 21

## Using the Sleeve Cutter Stop

When satisfied with the chosen cutting depth a sleeve cutter stop spacer is selected. The correct size of spacer is determined by the space inbetween the base of the instrument and the top of the femoral head. This is achieved using two methods; the spacers may be placed into the space until the desired size is selected (Figure 22). Alternatively a ruler maybe used to measure the space and then the corresponding sized spacer selected. 7 spacers are provided 8, 10, 12, 14, 16, 18 and 20 mm.

The sleeve cutter stop is now removed from the guide bar. The selected spacer is then placed onto the guide bar until it is in contact with the femoral head (Figure 23). The sleeve cutter stop may then be placed over the guide bar and advanced to the top of the spacer. The stylus is now passed around the femoral neck to confirm the intended cut depth is correct and no neck notching should occur.

When satisfied the sleeve cutter stop stylus is removed from the guide bar and the spacer left in place.

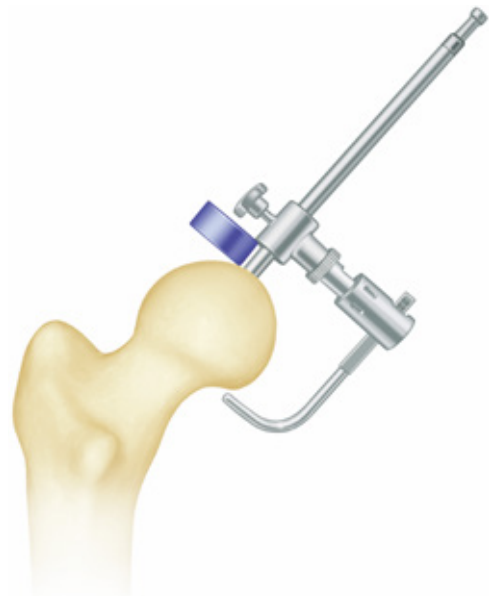


Figure 22



Figure 23

# Using the Sleeve Cutter Stop

Before femoral head preparation, the base of the femoral neck is packed with wet swabs to prevent bone debris entering the periarticular soft tissues. However, it is important to keep these swabs clear of the head so that they do not catch in the femoral cutter instruments.

The head/neck template is then positioned on the superior femoral neck as a second safe guard to protect the head/neck junction in the event of 'shoot through' (Figure 24).

The appropriate sleeve cutter is advanced. This should be done slowly and with care to ensure that 'shoot through' does not occur and also to ensure that femoral neck notching is not occurring. It should be noted that in most osteoarthritic femoral heads an eccentric amount of peripheral femoral head is regularly removed.

**NOTE: The assistant is key in keeping the femoral head in the centre of the wound.**

The sleeve cutter is advanced until it comes up against the spacer and cannot be advanced further (Figure 25 & 26). The sleeve cutter stop spacer is now removed.

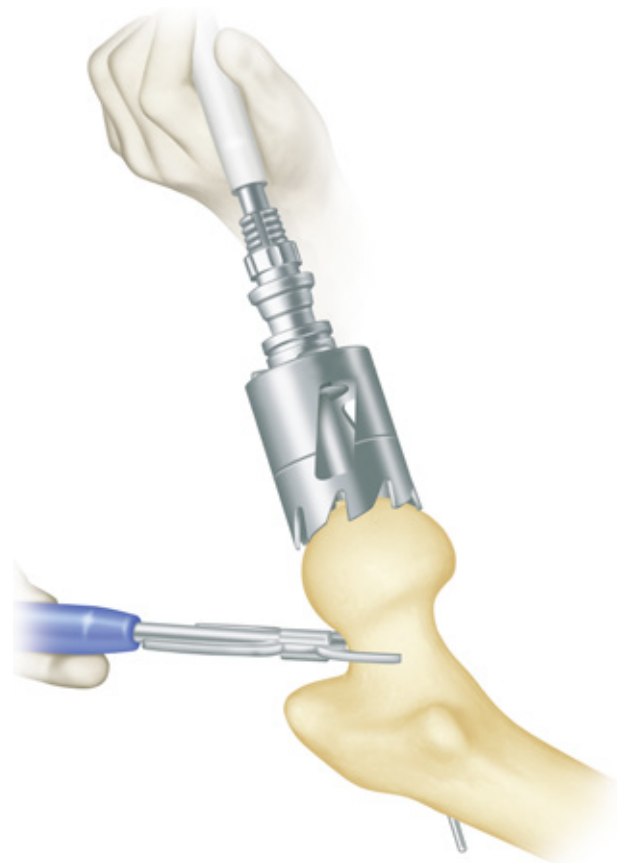


Figure 24



Figure 25



Figure 26



## Using the Sleeve Cutter Stop

The peripheral bone and any head/neck osteophytes should be trimmed off taking care not to strip any soft tissue attachments from the femoral neck (Figure 27 & 28).

The guide rod is pushed down the femur by hand until it is seated at the bottom of the prepared hole and left in its final position (Figure 29).

**NOTE:** Care should be taken that the thick aspect of the guide bar is now seated below the surface of the bone, as the thick aspect of the guide bar can act as a stop when using the plane cutter.

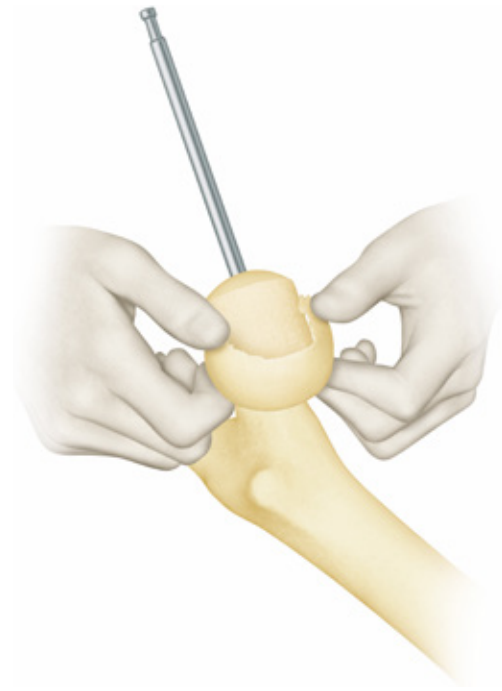


Figure 27

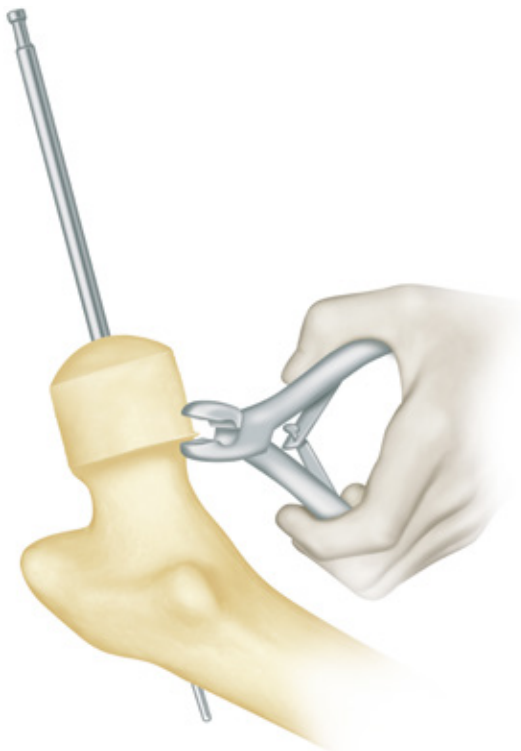


Figure 28



Figure 29

# Using the Sleeve Cutter Stop

**NOTE: Various methods of templating the desired amount of proximal bone to be removed may be employed.**

The sleeve cutter is advanced by hand over the previously prepared femoral head until the teeth meet the medial femoral head/neck junction (Figure 30). Once in correct position, a surgical marking pen is used to mark the resection line on the bone surface through the 'window' in the sleeve cutter.

Alternatively, the appropriate head/neck template is advanced over the prepared femoral head until the lower aspect meets with the medial head/neck junction. The surgical marking pen is used to mark the resection height which is indicated on the scale of the device (Figure 31).

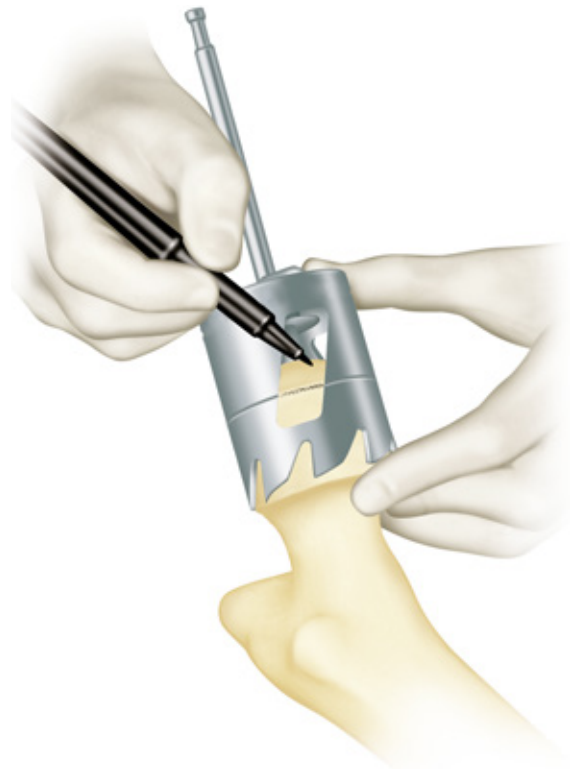


Figure 30

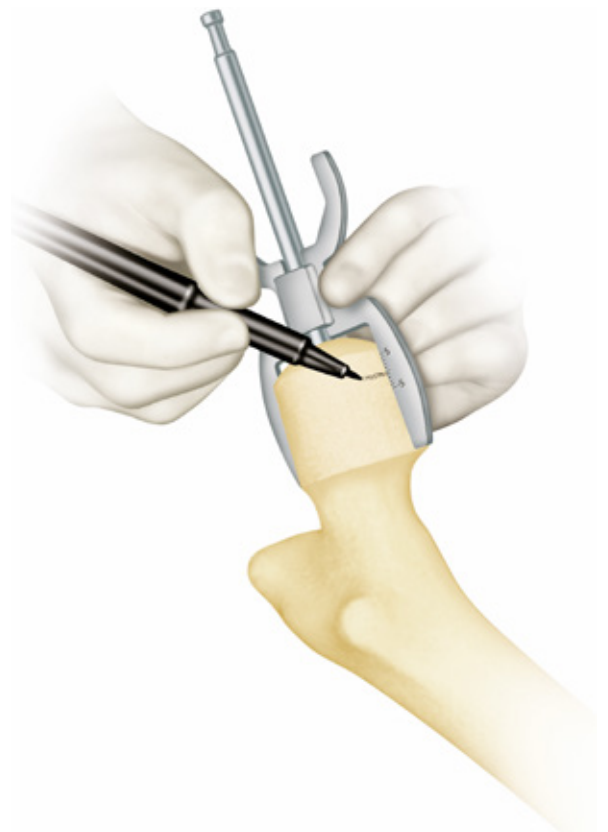


Figure 31

# Using the Sleeve Cutter Stop

The Plan Cutter is then advanced over the guide rod stopping at the marked resection line (Figure 32). Identify the marked resection line with the guide wire to aid visualisation.

To ensure correct bone resection, the head/neck template is to be advanced over the guide rod. Meeting the medial head/neck junction, bone has to point to the neutral (0) position of the device (Figure 33).

The appropriate chamfer cutter is used (Figure 34). It will usually be the case that the eccentricity of the femoral head disappears after chamfer cutting. Great care needs to be undertaken when using this instrument as considerable torque can be generated by the mixture of sclerotic and normal bone in the femoral head, so the instrument is advanced lightly and with regular irrigation. Experience has shown that high speed is advantageous and the powerdriver is set on drill rather than ream, thus giving high speed and low torque.

**NOTE: It is recommended to start all power tools away from bone before advancing over the guide rod. This keeps torque and stress to a minimum.**



Figure 32

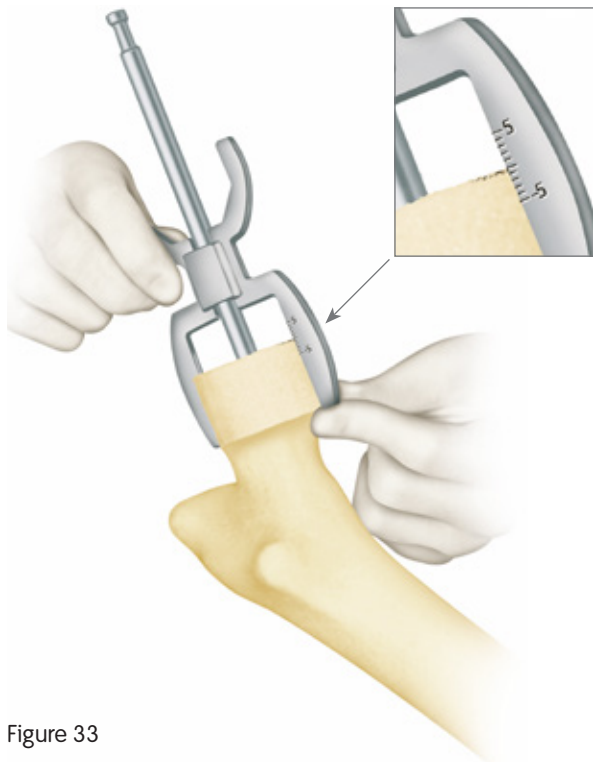


Figure 33



Figure 34

## Using the Sleeve Cutter Stop

A number of cement keyholes are drilled into the femoral head using the Wroblewski drill (Figure 35). At this stage any cysts are curetted. If the defects are relatively small, they are left and will be filled with cement. If the defects are substantial, they may be grafted with acetabular reamings prior to cementation.

The femoral head is thoroughly lavaged and brushed to open the cancellous network (Figure 36). With maximum rotation on the femur, the suction vent is inserted into the lesser trochanter (Figure 37). The femoral head can usually be kept free of blood until cementation occurs.



Figure 35

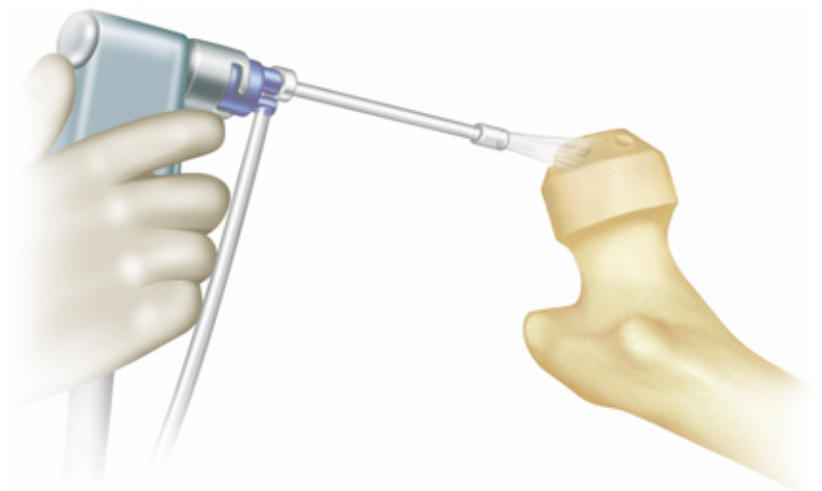


Figure 36



Figure 37

# Using the Stem Drill

The appropriately sized stem drill (tapered reamer) is used to enlarge the parallel hole to suitably fit the tapered stem of the femoral component. There are two sizes of stem drill (tapered reamer) which corresponds to 48-58 mm sized groups of femoral components as follows:

Size 2 = 46-52

Size 3 = 54-62

A mark is made on the femoral head/neck junction using the appropriate head/neck template over the guide rod (Figure 39) and surgical marker pen or electro-cautery to determine how far the prosthetic femoral head component should be advanced.

Impacting the prosthetic head to this mark ensures optimum pressurisation of cement into the open cancellous network, gives good support for the implant and ensures, as far as possible, the correct leg length. The guide bar is then removed.

Low viscosity cement is mixed and poured into the head implant. Alternatively, it can be drawn up into a bladder syringe and injected into the femoral component (Figure 40).

**NOTE: Low viscosity cement in sufficient quantity is used. High viscosity cement will prevent correct femoral component seating.**



Figure 38

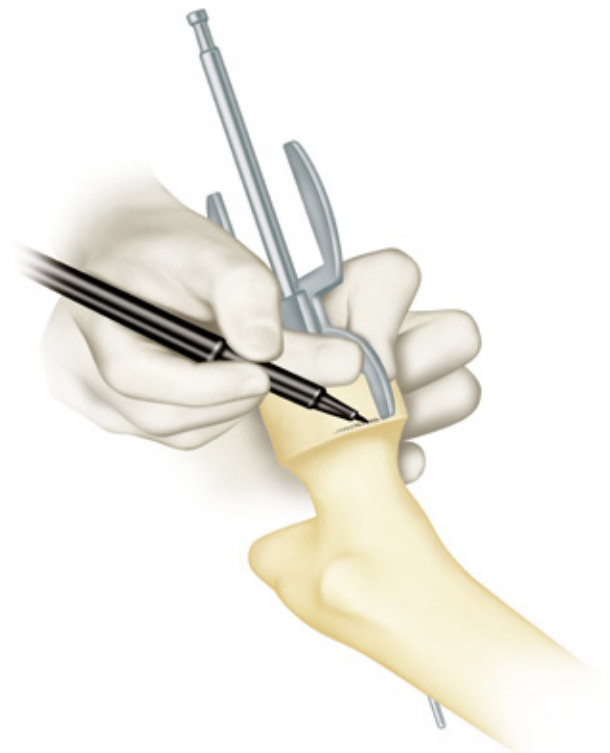


Figure 39



Figure 40

# Using the Stem Drill

One minute after the start of cement mixing, the femoral component is impacted into position to the previously made mark (Figure 41). It is important to have a swab positioned anteriorly to collect any extruded cement and to prevent this from flowing into the acetabular component. It is important not to get this swab caught between the femoral component and bone.

All extruded cement at the periphery of the femoral component is removed. Any remaining osteophytes at the femoral head/neck junction are excised (Figure 42) and the femoral head thoroughly cleaned with wet swabs and pulse lavage. The acetabular component is also thoroughly cleaned with pulse lavage and preparations made for reduction.

When traction and rotation are applied to the femur the femoral component can be cleanly located in the acetabular component. Scratching the femoral component against the edge of the acetabular component should be avoided and without trapping any capsule or synovial tissue between the femoral head and the acetabular component.

A check is made to ensure that no entrapment of soft tissue has occurred between the reduced components and a check is also made for stability and range of movement.

The femoral alignment pin is removed from the lateral femoral cortex (Figure 43) and the wound closed in layers using nylon for the fascia lata.

**NOTE: It is vital to remove the alignment pin from the femur and this should be recorded on the swab board.**

The patient is mobilised full weight bearing the following day and sticks abandoned between one and three weeks after operation as confidence and a normal gait allow.

Patients are allowed to sit on a normal height toilet seat or chair and sleep on their unoperated side as desired.

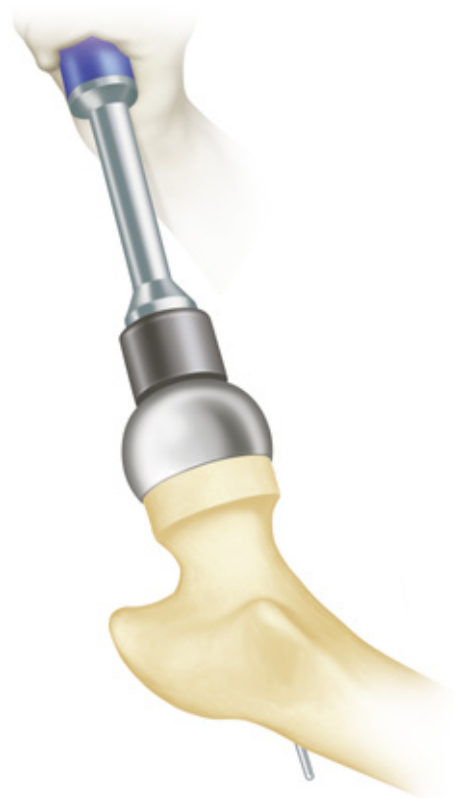


Figure 41



Figure 42

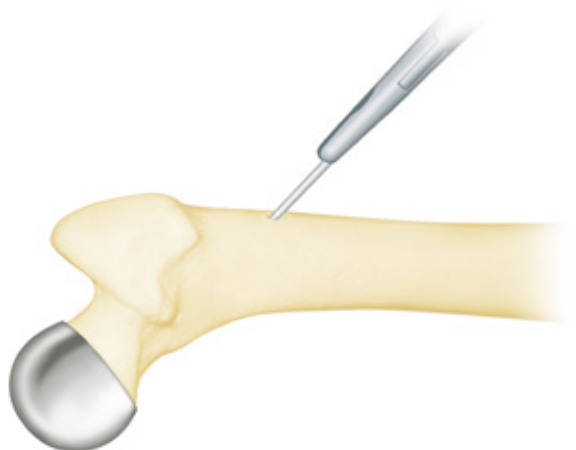


Figure 43

# Size Chart

The size chart (available as a wall chart) is presented to remind the surgeon of the femoral head and cup sizes that can be matched (Figure 44).

For example, the size 50 mm femoral component can be matched with a size 56 mm acetabular cup, a size 58 mm acetabular cup, a size 58 mm dysplasia cup. All these components have red coloured labels on their boxes.

**Never mix colors on heads and cups.  
Compatible femoral and acetabular components are all the same color.**

BHR <sup>®</sup> Implant Size Chart		smith&nephew BIRMINGHAM HIP <sup>®</sup> Resurfacing System	
HEAD SIZE	CUP SIZE	DYSPLASIA CUP SIZE	
48	54 56	56	
50	56 58	58	
52	58 60	60	
54	60 62	62	
56	62 64	64	
58	64 66	66	

IMPORTANT: NEVER mix colours on heads and cups.  
\* Trademark of Smith & Nephew 2015 412388

Figure 44 - Implant Size Chart Combined Sizes

# Dysplasia Cup

Where there is an obvious superolateral deficiency of the acetabulum, the option exists for the use of the BHR<sup>®</sup> Dysplasia Cup which uses a unique screw fixation to stabilise the acetabular implant.

The acetabulum should be reamed in the true hip centre position. In severe dysplasia it is desirable to bias the acetabular reamers in a posterior direction, to thin the thickened posterior acetabular wall and preserve the deficient anterior acetabular wall.

It is recommended to deepen the acetabular floor to the inner table to gain maximum superior cover in dysplasia. On occasions a slightly high hip centre will give enough support for a regular spherical cup. If there is not enough superior support for a spherical cup then the options are either augmentation of the acetabular roof with a structural allograft or the use of a BHR dysplasia cup and morcellised autografting of the acetabular defect.

In order that the screws engage bone, the dysplasia cup should be rotated anteriorly (not anteverted) from the neutral position (Figure 1). The cup is impacted to the floor of the acetabulum.

**NOTE: Do not cut the cables at this stage.**

Retract the polyethylene impactor cap and ensure satisfactory cup position. Always drill the posterior lug first as this is the drill hole most likely to miss the posterior ilium (Figure 2). If this happens, re-apply the cup introducer and reinsert the cup with more anterior rotation. Please note that excess anteversion and an excessively closed position of the acetabular component increase the chances of the posterior drill hole missing bone.

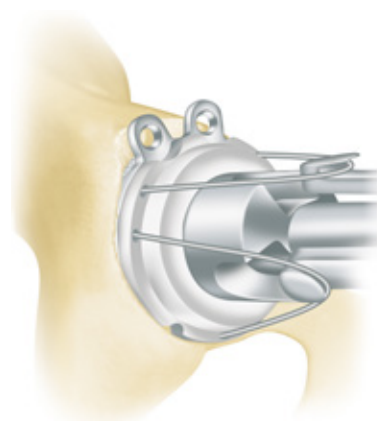


Figure 1

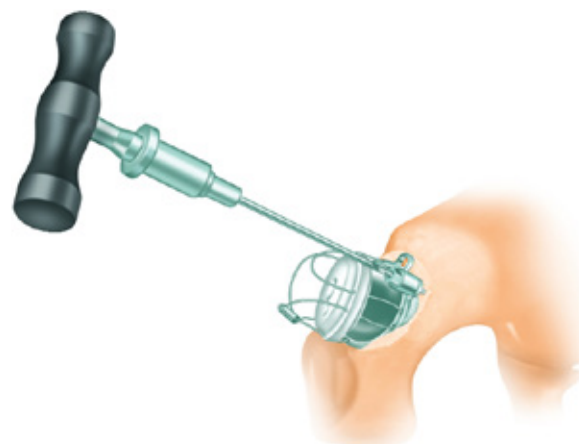


Figure 2



# Dysplasia Cup

The pilot drill guide should then be screwed into the posterior lug and a 3.2 mm drill passed to the inner cortex.

If the cup is positioned satisfactorily the pilot drill guide is then removed and the larger dysplasia screw drill is used to over-drill this hole through the lug, opening the canal to the screw core diameter. A depth gauge is used to gauge screw length. In severe dysplasia maximum screw length is desirable. In less severe dysplasia shorter screws can be used.

*Please note: these screws are neutralisation screws, they are not compression screws and if inserted correctly they are not distraction screws.*

A BHR<sup>®</sup> dysplasia self-tapping screw of appropriate length is then threaded through the lug using the socket provided and the screw driver handle (Figure 3). When the screw reaches the bone, longitudinal compression is applied as the screw engages the bone, thus preventing the cup from being pushed out of the acetabulum.

Once the screw is securely fixed in bone then power may be used to drive the screw home. This requires the high torque ream setting.

Final tightening is applied using the 'T' Handle and the screw head should sit flush on the lug face. The final tightening is engineered deliberately tight to prevent screw back out. The sequence is then repeated with the anterior lug (Figure 4). When both screws have been inserted the cables are cut and the polyethylene impactor cap removed. The author then usually inserts the femoral component before grafting the acetabular defect.

The false acetabulum is cleared of all soft tissue with a curette and the bone petalled with a gouge. The defect is grafted by impacting reamings into the defect between the cup and false acetabulum. This is then covered with surgical mesh for stabilisation.

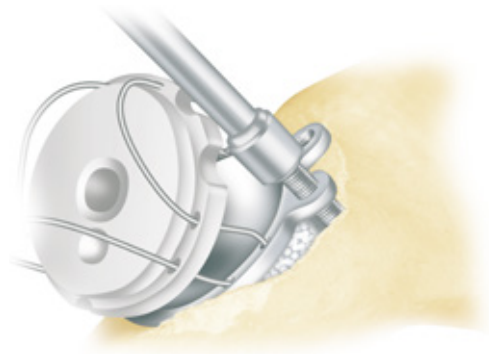


Figure 3

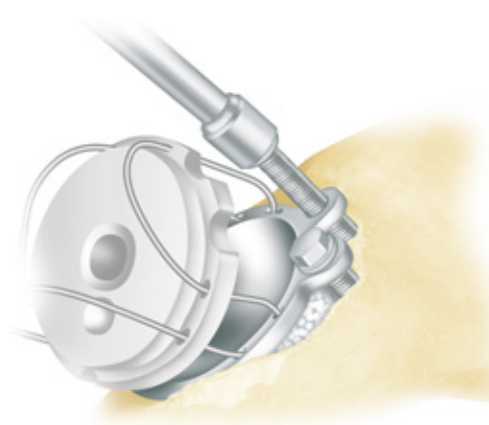


Figure 4

# Dysplasia Cup

With acetabular dysplasia the surgeon has to exercise judgement regarding the postoperative weight-bearing regime. In severe dysplasia the author has kept patients partial weight-bearing, using elbow crutches for six months, but in less severe dysplasia full weight bearing is permitted from the first postoperative day.

A typical regime for moderate dysplasia is partial weight bearing using elbow crutches for six weeks, followed by two sticks with gradually increasing activity over the next six weeks. We now have histological evidence of impressive bone ingrowth into the hydroxyapatite coated POROCAST® bone in-growth cup surface at six weeks. However, in severe dysplasia the designers prefer to see radiographic evidence of bone graft incorporation in the false acetabulum before allowing the patient to become fully active.

Additional screw fixation of the acetabular component by utilising the dysplasia cup may be desirable in certain non-dysplastic acetabulae. For example, the author has used this in old fractures of the posterior acetabular wall.

# Thrombo-embolic Prophylaxis

It seems clear that thrombo-embolism is much more of a problem following hip arthroplasty than with any type of soft tissue surgery. It is obvious that some factor in addition to venous stasis and endothelial damage is at work. This factor is bone marrow and fat embolisation caused by the insertion of a femoral component, particularly a cemented femoral component.

During preparation of the upper femur and insertion of a cemented THR femoral component, pressures up to 1400 mm Hg have been measured in the distal femur. These very high intramedullary pressures displace marrow and fat into the venous circulation. During hip dislocation from all surgical approaches the femoral vein is kinked and it is not until reduction of the prosthetic head into the acetabular component that marrow and fat gush into the right heart and pulmonary circulation.

Application of the cemented femoral component of the BIRMINGHAM HIP<sup>®</sup> Resurfacing (BHR<sup>®</sup>) System also raises the femoral intramedullary pressure, but the amount of fat displaced is much less than with a cemented stemmed THR.

In an effort to prevent the small amount of fat displacement known to occur with resurfacing, it is recommended to use a method of suction venting of the femur during femoral preparation and component insertion. A hole is drilled through the lesser trochanter and a cannula is inserted into the centre of the femoral canal. This is attached via extension tubing to a second suction unit. During insertion of the cemented femoral component there is an impressive amount of fat and marrow removed from the femur.

Up to 100ml of fat, blood, irrigation fluid and marrow can be seen in the suction unit. Limited investigation by trans-oesophageal echocardiography at this stage shows that fat embolisation is nearly or completely eliminated by venting. This work is at a very early stage of development but is presented for interest.

# Acetabular Cup Extraction Kit (Cat. no. 900-201)

## Instructions for Use

### Intended Use

The Acetabular Cup Extraction Kit is intended for use to remove acetabular components of the BIRMINGHAM HIP<sup>®</sup> Resurfacing device during revision operations.

### Sterility

The Acetabular Cup Extraction Kit is provided sterile for SINGLE USE ONLY. The sterilisation method is gamma irradiation with a minimum of 25 kGy and a maximum of 35 kGy. The Acetabular Cup Extraction Kit must not be resterilised by the user.

### Mixing of Components

This kit should never be used in conjunction with other manufacturer's implants or instruments.

### Indications

The indication for use of this kit includes all revision operations where revision of the BHR acetabular cup is necessary.

### Contraindications

None.

For more information on the BIRMINGHAM HIP<sup>®</sup> Resurfacing System please see the General Information Leaflet enclosed with each implant and the operative technique.

### Introduction

To extract an implanted Smith & Nephew BHR Acetabular Cup, a cable must first be threaded through the 3 wormholes and joined with a metal collar using a special knot. This provides three loops of cable for the extraction/impaction tool to attach to via a plastic spacer. The cup can then be manipulated or hammered out using a slide hammer.

### Instructions

Two types of cable are supplied with the extraction kit, a plastic coated cable and an uncoated cable. As a first attempt, lace the acetabular cup with the plastic coated cable. Thread the cable through the worm holes leaving loops large enough to fit over the impaction / extraction tool with the plastic spacer attached, shown in Figure 1.



Figure 1

For convenience the knot should be tied without the extraction tool in place. Pass the cable ends through the metal collar, as shown in Figure 2, leaving approximately 5cm (2") of the free ends protruding.



Figure 2

# Acetabular Cup Extraction Kit (Cat. no. 900-201)

Pass each end back through the metal collar to form small loops, just large enough to pass the cable through. (Figure 3a and 3b). Ensure that there is approximately 4cm (1.5") of free cable end after it has been passed through the metal collar.



Figure 3a

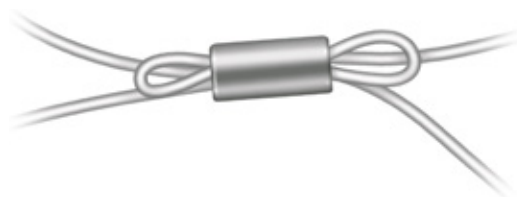


Figure 3b

Pass each free end over the metal collar and back through its own loop (figures 4a and 4b). It may be necessary to pinch the cable down onto the metal collar in order to keep the cable ends within the loops. The knot is now formed and ready to be tightened using the extraction tool.



Figure 4a

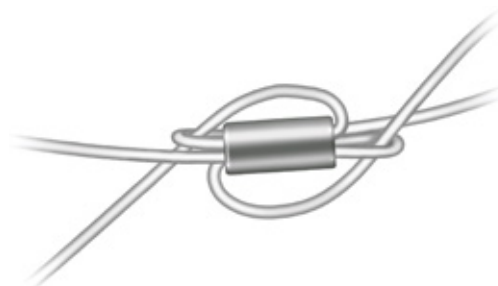


Figure 4b

Once the knot has been formed attach the plastic spacer to the extraction tool and insert the extraction tool into the acetabular cup. Pass the cable loops over the ends of the extraction tool. It may be necessary to adjust the cable lengths to ensure that the cable loops pass over the tool and plastic spacer. It may also be necessary to reposition the knot, so that it lies mid way between the extraction tool and the acetabular cup. Slowly begin to tension the cable loops. As this is done, the knot will begin to tighten. During this process, ensure that the spare cable has been pulled through the loops and that the cable is flush to metal collar. Continue to tighten until the knot is secure. The cup can now be extracted by attaching a slide hammer to the extraction tool. During extraction it may be necessary to re-tension the cables.

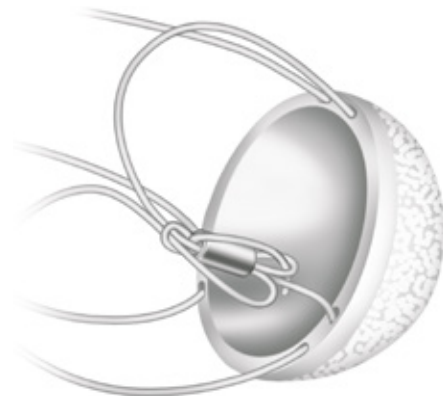


Figure 5

If the acetabular cup is well fixed the plastic coated cable may break. If this occurs, remove the broken cable and replace it with the uncoated cable. To help thread the thicker uncoated cable, the ends should be shaped into a curve.

## Further Information

For further information on the Acetabular Cup Extraction Kit, please contact Smith & Nephew Orthopaedics Ltd.

# BIRMINGHAM HIP<sup>◇</sup> Resurfacing (BHR<sup>◇</sup>) System

## Important Medical Information Warnings and Precautions

### DEVICE DESCRIPTION

The BIRMINGHAM HIP Resurfacing (BHR) prosthesis is a metal-on-metal hip resurfacing prosthesis. The device consists of a stemmed femoral head resurfacing component designed for cemented fixation, and a hemispherical acetabular cup designed for cementless, press-fit, fixation. The acetabular cups are configured in one-piece designs. Instrumentation sets are provided as standard; several additional instruments are available as options.

#### Resurfacing Femoral Head

The resurfacing femoral head is supplied in a range of eight sizes, and is manufactured from CoCr alloy. The femoral head central stem is parametric and varies proportionally with the external diameter. There are 6 equally spaced internal recesses intended to provide antirotational locking for the cement mantle.

#### Acetabular Cups

The standard acetabular component is supplied in a range of fourteensizes). For those patients with a deficiency in the superolateral aspect of the acetabulum, the dysplasia cup is available. The dysplasia cup is designed with two superolateral screw holes that accommodate CoCr-alloy dysplasia cup screws. There is a range of six sizes for the dysplasia cup. Acetabular cups have a single layer of integrally-cast CoCr-alloy (ASTM F75 and ISO 5832-4) beads on the outer surface that are coated with hydroxyapatite (HA) (ASTM F1185).

#### Screws for Acetabular Cups

The dysplasia cup screws are threaded through a threaded lug on the superolateral aspect of the dysplasia cup and lock in situ. The screws also lock into the posterior cortical bone of the ilium. Screws are available in sizes ranging from 24mm to 88mm, in 4mm increments.

### Materials

Component	Material
BHR Femoral Heads	cobalt chrome alloy per ASTM F75 and ISO 5832-4
BHR Acetabular Cups	cobalt chrome alloy per ASTM F75 and ISO 5832-4, HA (coating) per ASTM F-1185
Dysplasia screws	CoCr alloy per ASTM F-1537/ISO 5832-12

### Sizing and System Compatibility – Acetabular Cups

Each femoral head resurfacing component is compatible with standard acetabular cup sizes and dysplasia sizes (Table 1).

**Table 1: BHR Head and Cup Sizing and System Compatibility**

BHR Femoral Head Resurfacing Component <i>(identified by head outer diameter)</i>	Mating BHR Standard Cup Sizes	Mating BHR Dysplasia Cup Sizes
48mm	54mm or 56mm	56mm
50mm	56mm or 58mm	58mm
52mm	58mm or 60mm	60mm
54mm	60mm or 62mm	62mm
56mm	62mm or 64mm	64mm
58mm	64mm or 66mm	66mm
60mm	66mm	
62mm	68mm	

### INDICATION FOR USE

The BIRMINGHAM HIP Resurfacing (BHR) System is a single use device intended for hybrid fixation: cemented femoral head component and cementless acetabular component. The BHR System is intended for use in patients requiring primary hip resurfacing arthroplasty due to:

- Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia/DDH, or
- Inflammatory arthritis such as rheumatoid arthritis.

The BHR System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision.

# BIRMINGHAM HIP<sup>◇</sup> Resurfacing (BHR<sup>◇</sup>) System

## CONTRAINDICATIONS

- Patients who are female
- Patients with infection or sepsis
- Patients who are skeletally immature
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Patients with bone stock inadequate to support the device including:
  - Patients with severe osteopenia or patients with a family history of severe osteoporosis or severe osteopenia.
  - Patients with osteonecrosis or avascular necrosis (AVN) with >50% involvement of the femoral head (regardless of FICAT Grade).
  - Patients with multiple cysts of the femoral head (>1cm).
  - Note: In cases of questionable bone stock, a DEXA scan may be necessary to assess bone stock status.
- Patients with known moderate to severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who are severely overweight
- Patients with known or suspected metal sensitivity (e.g., jewelry)

## WARNINGS AND PRECAUTIONS

- Patients who, from plain radiograph pre-operative templating, appear to require 48mm femoral heads should not be considered as candidates for BHR implantation. Patients requiring a 48mm femoral head size are at a moderately elevated risk of requiring revision surgery earlier than expected. While Smith & Nephew concluded that the increased risk associated with this head size does not outweigh the potential benefit to the patient in the specific circumstance of intra-operative downsizing from a pre-operatively templated 50mm to a measurement of 48mm at the time of surgery, surgeons should use their best medical judgment to consider this information relative to the patient's overall medical history and prognosis in determining its appropriateness as a surgical treatment

- Patients on medications (such as high-dose or chronic aminoglycoside treatment) or with co-morbidities (such as diabetes) that increase the risk of future, significant renal impairment should be advised of the possibility of increase in systemic metal ion concentration. Preoperative and postoperative monitoring of renal function (such as creatinine, GFR, BUN) will be necessary for these patients.
- Only physicians who have received appropriate training and are familiar with the implant components, instruments, procedure, clinical applications, adverse events, and risks associated with the BHR System should use this device. Contact Smith & Nephew Orthopaedics Ltd. for the surgical technique manual and procedural training protocol.
- Based on literature reports together with the manufacturer's post-market data, the following were identified as risk factors for early revision:
  - Patients who receive a 48mm femoral head;
  - Patients who receive a device which is incorrectly positioned;
  - Patients who have a diagnosis of avascular necrosis;
  - Patients who have congenital dysplasia; and
  - Patients who are obese

The more risk factors a patient has, the greater the risk of procedure failure requiring a revision of the hip.

## Preoperative

- Do NOT use any component of the BHR System with another manufacturer's implant components, because designs and tolerances may be incompatible.
- Do NOT use cobalt chrome BHR System components with any stainless steel components, since corrosion can occur between two dissimilar metals.
- Previous hip surgery such as osteotomy, core decompression, hemi resurfacing, or internal fixation may increase the risk of early failure.
- Examine instruments for wear or damage before use. While rare, intra-operative instrument breakage can occur. Instruments that have experienced excessive use or force may be susceptible to breakage.

# BIRMINGHAM HIP<sup>◇</sup> Resurfacing (BHR<sup>◇</sup>) System

- If during pre-operative planning an appropriately sized component cannot be found, this type of prosthesis should not be used.

## **Intraoperative**

- Implants should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew Orthopaedics Ltd.
- Avoid notching the femoral neck, as this may lead to femoral neck fracture.
- Avoid placing the femoral component in varus. Varus placement of the femoral component has been associated with femoral neck fracture.
- When performing a hip resurfacing procedure with the BHR acetabular cup, the cup must be used ONLY with a BHR Femoral Head. If the surgeon abandons the BHR resurfacing procedure in favor of a total hip replacement, the BHR cup must not be used.
- Do NOT re-use an implant. All implants are intended for single-use only.
- Use the recommended instruments and the recommended surgical technique.
- Improper selection, placement, positioning, and fixation of the implant components may result in early implant failure.
- Malalignment of the components and/or soft tissue imbalance may cause excessive wear and early implant failure.
- Associated trials and templates should be used for verification of component size. If an appropriate component size cannot be found during pre-operative planning, do not use this type of implant.
- Complete pre-closure cleaning of the implant site (complete removal of bone chips, bone fragments, metallic debris, etc.) is critical to prevent wear of the articular surfaces.
- Using instruments other than the associated BHR instruments may result in inaccurate placement.

## **Hydroxyapatite-Coated Acetabular Implants**

- Do NOT allow the HA-coated, porous-surfaced acetabular component to contact any substance other than the device packaging, clean gloves, or the patient's tissue.
- Do NOT use cement with these HA-coated, porous-surfaced implants.

- Take care to achieve a stable press fit. The HA-coated, porous surface is not intended to compensate for inadequate implant fixation.

## **Postoperative**

- Excessive physical activity levels, excessive patient weight, and trauma to the joint replacement may cause early failure of the implant.
- Loosening of components may increase production of wear particles and accelerate damage to the bone, making successful revision surgery more difficult.

## **Patient Education**

- Warn the patient of the surgical risks, possible adverse effects, and possible operative complications that can occur with joint arthroplasty.
- Warn the patient of the limitations of artificial joint replacement devices.
- Caution the patient to protect the joint replacement from unreasonable stresses and to follow the treating physician's instructions. In particular, warn the patient to strictly avoid high impact activities such as running and jumping during the first post-operative year while the bone is healing.
- Warn the patient that artificial joint replacement devices can wear out over time, and may require replacement.

## **POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH**

### **Reported Device Related Adverse Effects**

The most commonly reported BHR device related adverse events are:

- femoral neck fracture
- femoral head collapse
- infection
- avascular necrosis
- dislocation
- component migration/loosening, and
- impingement

### **Potential Adverse Effects**

The following adverse effects may occur in association with hip replacement surgery including the BHR System:

- Cardiovascular complications including venous thrombosis, pulmonary embolism, or myocardial infarction



# BIRMINGHAM HIP<sup>◇</sup> Resurfacing (BHR<sup>◇</sup>) System

- Sudden, pronounced, intraoperative blood pressure decrease due to the use of bone cement
- Hematoma or damage to blood vessels resulting in large blood loss
- Delayed wound healing
- Superficial or deep infection. Infections may occur months to years after surgery and these infections are difficult to treat and may require reoperation with removal surgery and later replacement at another time
- Temporary or permanent nerve damage resulting in functional and/or sensory deficits in the affected limb
- Metal sensitivity reactions or allergic reactions or metallosis
- Dislocation or subluxation leading to post-operative joint instability (which may be caused by malpositioning of the implants, or muscle or fibrous tissue laxity)
- Component loosening or migration due to trauma, loss of fixation, malalignment, or bone resorption
- Limb length discrepancy
- Increased hip pain and/or reduced hip function
- Fatigue fracture of the implants as a result of excessive loading, malalignment, or trauma
- Osteolysis and/or other peri-prosthetic bone loss
- Unintended bone perforation or fracture occurring either intra-operatively or post-operatively as a result of trauma, excessive loading, osteolysis, or osteoporosis
- Periarticular calcification or ossification
- Wear or deformation of the articular surface as a result of excessive loading or implant malalignment
- Temporary or permanent device related noise such as clicking or squeaking
- Inflammatory tissue response to high levels of wear debris resulting in peri-prosthetic aseptic lymphocyte dominated vasculitis associated lesions (ALVAL), fluid collections, or soft tissue masses (Pseudotumors)

Any of these adverse effects may require medical or surgical intervention. Rarely, these adverse effects may lead to death.

## STERILISATION

- Implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10<sup>-6</sup>. Metal components are sterilized to a minimum of 25 kiloGrays of gamma irradiation. All components are supplied in protective packaging. Inspect packages for punctures or other damage prior to surgery.
- Instruments used to implant the device system are supplied non-sterile and must be sterilized prior to use using one of the following validated, recommended methods:

**\*Prevacuum Flash Cycle:** 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum exposure time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge

**\*High Temperature Gravity Cycle:** 270°F to 275°F (132°C to 135°C) with a minimum exposure time of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying.

**\*Prevacuum Cycle:** 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum exposure time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying.

- DO NOT RESTERILIZE implant components. Contact your local Smith & Nephew Sales Representative regarding procedures to return components to Smith & Nephew Orthopaedics Ltd..

The product is not labeled “pyrogen free”.

The BHR femoral head and BHR acetabular cup components are packaged in a dual sterile barrier blister tray to maintain sterility. The products have a five (5) year sterile shelf-life where the sterile barrier is not broken.

## MRI SAFETY INFORMATION

Smith & Nephew, Inc. BIRMINGHAM HIP<sup>◇</sup> Resurfacing (BHR) System implants are manufactured from a non-ferromagnetic material, cobalt-chromium-molybdenum alloy. Smith & Nephew has performed non-clinical Magnetic Resonance Imaging (MRI) studies on BHR implants which are 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.

# BIRMINGHAM HIP<sup>◇</sup> Resurfacing (BHR<sup>◇</sup>) System

## MR Information

Non-clinical testing has demonstrated the BHR System is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) and 3.0-Tesla (3.0T)
- Spatial gradient field of 3,000 Gauss/cm (30.0 Tesla/m) or less
- Maximum whole body specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of continuous scanning
- Normal operating mode of the MR system. The effects of MRI procedures using MR systems and conditions above these have not been determined

## MR Heating

Non-clinical testing was performed according to ASTM F2182-09 and yielded the following:

### 1.5 Tesla

The BHR System produced a temperature rise of less than 7.5 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.1 W/kg, as assessed by calorimetry for 15 minutes of continuous MR scanning in a (field strength – 1.5T) (model - Intera) (manufacturer – Philips Medical Systems (PMS)) (software version – Release 12.6.1.4 (11/5/2012)) MR scanner.

### 3.0 Tesla

The BHR System produced a temperature rise of less than 4.4 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg, as assessed by calorimetry for 15 minutes of continuous MR scanning in a (field strength - 3T) (model - Signal Hdxt) (manufacturer - General Electric (GE) Medical Systems) (software version- 15.0\_M4\_0910.a) MR scanner.

## Image Artifacts

MR image quality may be compromised if the area of interest is relatively close to the position of the device. Distortion extended as much as 10.2 cm from the implant in image distortion tests performed according to ASTM F2119-07 in a 3.0 T MR system. Therefore, it may be necessary to optimize MR imaging parameters for the presence of these implants.

## Information

For further information, please contact Smith & Nephew Orthopaedics Ltd., Customer Service:  
+44 (0) 845 056 8333

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