The requirements of a surgical approach to the hip for arthroplasty are firstly an adequate exposure allowing good visualization and optimum component insertion, and secondly the minimum of damage to the neuromuscular structures around the hip.

In conventional stemmed total hip replacement it is resection of the femoral head that affords easy visualization of the acetabulum with many surgical approaches to the hip. With resurfacing, this additional help in the surgical exposure is clearly not an option.

In an elderly, inactive patient undergoing THR, a degree of neuromuscular damage, inevitable in certain surgical approaches, seems compatible, at least in some cases with reasonable functional outcome. In a younger active patient undergoing hip resurfacing however, such neuromuscular damage produces an unacceptable limited functional outcome.

Over the past 10 years I have tried most surgical approaches for hip resurfacing. For reasons of good exposure, rapid rehabilitation and normal hip function, the posterior approach is strongly recommended. Trochanteric osteotomy gives a splendid extensile exposure and may be useful if a hip ankylosis is to be tackled. The osteotomised fragment should be small, and great care needs to be paid to trochanteric re-attachment and patient rehabilitation if trochanteric escape and non-union is to be avoided.

It is not reasonable to select a highly sophisticated device like the BIRMINGHAM HIP™ Resurfacing (BHR™) System and then damage the abductor muscles or their nerve supply in the surgical approach, use forcible retraction causing muscle tearing and heterotopic ossification, malposition the components due to poor visualization, and still expect a good result.

In a personal experience of over 2000 hip resurfacings it has been very gratifying to see patients recover excellent function after this procedure and lead a normal lifestyle, including participation in recreational and competitive sport.

No operative technique manual can be entirely comprehensive, but the steps included in this brochure are considered to be the essential elements in adopting this surgical procedure.

Derek McMinn FRCS
Consultant Orthopaedic Surgeon
Nota Bene

The technique description herein is made available to the healthcare professional to illustrate the suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.
Indications for use

The BIRMINGHAM HIP™ Resurfacing System (BHR™) 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 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 with a family history of severe osteoporosis or severe osteopenia
  - Patients with osteonecrosis or avascular necrosis (AVN) with >30% 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 inadequate bone stock
- Females of child-bearing age due to unknown effect on the fetus of metal ion release
- 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 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.

- 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, Inc. for the surgical technique manual and procedural training protocol.

- Currently, Smith & Nephew, Inc. does not have a commercially available metal femoral head and stem (monoblock or modular) for use with a BHR resurfacing cup (one-piece or modular). Therefore, if the BHR resurfacing head must be revised to a total hip arthroplasty, the one-piece BHR acetabular cup must also be revised, even if well fixed; however, in the case of a modular cup, the R3™ Acetabular Shell can remain in place if well-fixed, and the R3 Metal Liner must be replaced with an R3 Poly Liner, which can be used with any compatible legally marketed Smith & Nephew femoral stem and mating ceramic or metal femoral head component.

- Based on literature reports and the clinical study, the following were identified as risk factors for revision: Patients who are female; who receive a smaller component size (≤ 44mm); have the device implanted at a high abduction angle; are obese; or, who have a diagnosis of avascular necrosis have a greater risk of revision than other patients. The more risk factors a patient has, the greater the risk of procedure failure requiring a revision to 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 Resurfacing device may be implanted through various hip surgical approaches. The posterior approach, as described by Derek McMinn FRCS is described in this operative technique.

Other surgical approaches to the hip may be used however, the posterior approach is favoured by the designer surgeon and his submitted clinical data is based on this approach.
Pre-Operative 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 (Figure 3).

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 (Figure 3). 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.
Intra-Operative 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 utilized. 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 4,5).

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

If the antero-inferior 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 2mm less than the definitive acetabular component to be inserted (Figure 6).

In large patients with soft cancellous bone 3mm under-reaming is recommended. In small patients with sclerotic acetabulae 1mm 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 1mm smaller than the definitive component size (Figure 7).

Postero-inferior and antero-inferior 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 8).

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

High Performance Cup Introducer Inspection Procedure

The following instructions should be followed to maintain the performance of the BHR® 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.
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 9).

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 10). 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

When attaching the cup using the wires and cup introducer, tension should be applied until the cup is securely attached to the introducer assembly. Care should be taken with over tightening and excessive wire tension as this may lead to wire breakage.

** Acetabular Cup Introducer

** Wire Removal Procedure

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

- Use appropriate wire cutters, in good condition, for the cutting task.
- Minimize 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.
Curved Cup Introducer

These instructions provide important information regarding assembly and wiring for use of the BHR® curved cup introducer.

NOTE: This curved cup introducer is for use with BHR Resurfacing cups only. It is advised that when using Dysplasia & Bridging cups the standard straight Introducer should be used.
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.

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).

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

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).
X-Bar

The X-Bar is attached to the curved Cup Introducer. (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
Femoral Preparation

The desired position of the femoral alignment pin will be known from the pre-operative 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).
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 5mm above the outer fibres of vastus lateralis.

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

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.
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 visualization (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 stabilized. Fine-tuning of this position can then occur.
Templating

BHR® template sets 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 6).

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 (A). 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 (B).

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 7) is overlayed with the centre line of the implant template to identify the pin insertion point on the intertrochanteric crest (C). This measurement is translated intraoperatively onto the patient’s femur using the measuring guide (Figure 8) 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.
The measuring guide is placed on the tip of the lesser trochanter translating the pre-operative measurement on to the intertrochanteric crest. The alignment pin insertion point can now be marked (Figure 9).

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 10).

**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 11).

The operation of the short arm jig remains consistent with the traditional McMinn alignment jig as described earlier in this BHR 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.
A guide wire is inserted when the desired position of the alignment guide has been achieved. (Figure 12).
The central rod is removed and the guide assembly completely removed.

**NOTE:** Guide wires are intended for single use only. Re-use of the guide wires may lead to breakage.

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 13).

**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 pressurization 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.
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 14).

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 15).

The most stability is achieved when the thicker lower aspect of the guide rod is placed flush with the bone (Figure 16).
Using the Sleeve Cutter Stop

Smith & Nephew have developed the BIRMINGHAM HIP® Resurfacing (BHR®) Sleeve Cutter Stop 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 visualize 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 17).

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 18).
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 19).

The positioning of the tip of the stylus denotes the depth the sleeve cutter will cut to (Figure 20)
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 21 & 22)
When satisfied with the chosen cutting depth an sleeve cutter stop spacer is selected. The correct size of spacer is determined by the space in between the base of the instrument and the top on the femoral head. This is achieved using two methods; the spacers may be placed into the space until the desired size is selected (Figure 23). Alternatively a ruler maybe used to measure the space and then the corresponding sized spacer selected. 6 spacers are provided 10, 12, 14, 16, 18 and 20mm.

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 24). 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.
Before femoral head preparation, the base of the femoral neck is packed with wet swabs to prevent bone debris entering the peri-articular 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 25).

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 osteo-arthritisic 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 26 & 27). The sleeve cutter stop spacer is now removed.
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 28, 29).

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 30).

**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.
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 31). 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 32).
The Plan Cutter is then advanced over the guide rod stopping at the marked resection line (Figure 33). Identify the marked resection line with the guide wire to aid visualization.

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 34).

The appropriate chamfer cutter is used (Figure 35). 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.
A number of cement keyholes are drilled into the femoral head using the Wroblewski drill (Figure 36). 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 37). With maximum rotation on the femur, the suction vent is inserted into the lesser trochanter (Figure 38). The femoral head can usually be kept free of blood until cementation occurs.
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 three sizes of stem drill (tapered reamer) which correspond to sized groups of femoral components as follows:-

Size 1 = 38-44
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 40) 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 pressurization 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 41).

NOTE: Low viscosity cement in sufficient quantity is used. High viscosity cement will prevent correct femoral component seating.
One minute after the start of cement mixing, the femoral component is impacted into position to the previously made mark (Figure 42). 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 43) 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 44) 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 mobilized 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.
Size Chart

The size charts (available as a wall chart for classic sizes and combined sizes) are presented to remind the surgeon of the femoral head and cup sizes that can be matched (Figure 45 & 46).

For example, the size 50mm femoral component can be matched with a size 56mm acetabular cup, a size 58mm acetabular cup, a size 58mm dysplasia cup, or a size 62mm bridging 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.
Where there is an obvious superolateral deficiency of the acetabulum, the option exists for the use of the BHR™ Dysplasia Cup which uses a unique screw fixation to stabilize 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.
The pilot drill guide should then be screwed into the posterior lug and a 3.2mm 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 neutralization screws, they are not compression screws and if inserted correctly they are not distraction screws.

A BHR™ 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 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 stabilization.
With acetabular dysplasia the surgeon has to exercise judgement regarding the post-operative weight-bearing regime. In severe dysplasia we recommend keeping the patients partial weight-bearing, using elbow crutches for six months, but in less severe dysplasia full weight bearing is permitted from the first post-operative 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 ingrowth cup surface at six weeks. However, in severe dysplasia we recommend 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 utilizing the dysplasia cup may be desirable in certain non-dysplastic acetabulae. For example, in old fractures of the posterior acetabular wall, the bridging acetabular cup (useful in gross femoral head/acetabulum size mis-match) also has superolateral lugs for screw fixation. In these non-dysplastic acetabulae, the edge of the superior acetabulum impinges on the lugs, thus preventing complete seating of the acetabular component. Therefore the operating surgeon may utilize a surgical burr to facilitate placement of the lugs without compromising the acetabular orientation.
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 embolization 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 1400mm 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.

Any surgeon who has observed this fat embolization with trans-oesophageal echocardiography following insertion of a cemented femoral component of a THR cannot fail to be amazed by the resilience of the human to survive such an assault. (Figure 1).

It is quite remarkable how few patients develop acute circulatory collapse or clinical fat embolism syndrome following cemented THR. However this displaced marrow is rich in tissue thromboplastin and this acts as a potent activator of the clotting system. It is this activation of the clotting cascade by displaced fat and marrow, in addition to venous stasis and endothelial damage, that gives our thrombo-embolic problems.

Application of the cemented femoral component of the BIRMINGHAM HIP™ Resurfacing (BHR™) System also raises the femoral intra-medullary pressure, but the amount of fat displaced is much less than with a cemented stemmed THR (Figure 2).
In an effort to prevent the small amount of fat displacement known to occur with resurfacing, the author has been using 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 (Figure 3).
Instruction for Use

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

Sterility
The Acetabular Cup Extraction Kit is provided sterile for SINGLE USE ONLY. The sterilization method is gamma irradiation with a minimum of 25 kGy and a maximum of 35 kGy. The Acetabular Cup Extraction Kit must not be resterilized 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 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.

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.
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.

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.

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.

It is recommended to free the components from the host bone with curved rongeurs or appropriate method before proceeding.

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.
## BHR® Resurfacing Head

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## BHR Acetabular Cup

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### BHR Dysplasia Cup

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### BHR Cup Screw

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Each BHR femoral head resurfacing component is compatible with only one R3™ Metal Liner size. The R3 Metal Liners are compatible with the R3 Acetabular Shells as shown in Table 2.

### Acetabular Cups - Modular

The R3™ Acetabular Shells are supplied in a range of ten sizes (accommodating femoral heads in sizes from 38mm to 54mm) and in versions with and without acetabular screw holes. The R3 Acetabular Shells contain an asymmetric porous beaded coating (STK11T). The mating R3 Metal Liner is assembled to the R3 Acetabular Shell through a taper locking mechanism. The R3 Metal Liners are available in nine sizes to accommodate BHR Femoral Heads from 38mm through 54mm.

### Screws for One-Piece Cups

The dysplasia cup screws are threaded through a threaded lug on the superolateral aspect of either the dysplasia or bridging 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 86mm, in 4mm increments.

### Screws and Plugs for Modular Cups

The R3 Acetabular Shells with acetabular screw holes are compatible with Spherical Head Screws, which are available in lengths of 15, 20, 25, 30, 35, 40, 45, 50, 60, and 70mm. If the surgeon wishes to seal the apex hole or any unused acetabular screw holes, Screw Hole Caps and Apex Hole Covers are available.

### Materials

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
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<tbody>
<tr>
<td>Femoral heads, R3 Metal Liners</td>
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<tr>
<td>One-piece BHR Acetabular Cups</td>
<td>cobalt chrome alloy per ASTM F75 and ISO 5832-4; HA coating per ASTM F 1185</td>
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<tr>
<td>R3 Acetabular Shells (modular)</td>
<td>Ti-6Al-4V alloy per ASTM F-1472 and ISO 5832-3; 2 beadlet, CP Titanium per ASTM F-67 and ISO 5832-2 (STK11T)</td>
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<tr>
<td>Dysplasia screws</td>
<td>CoCr alloy per ASTM F13-373/ISO 5832-12</td>
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<tr>
<td>Acetabular screws, screw hole plugs, apex hole plugs</td>
<td>Ti6AlV alloy per ASTM F-1472 and ISO 5832-3</td>
</tr>
</tbody>
</table>

### WARNING AND PRECAUTIONS

- **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 osteoporosis should not receive a BHR procedure. 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 should not receive a BHR.
  - Patients with multiple cysts of the femoral head (>1cm) should not receive a BHR.
  - Note: In cases of questionable bone stock, a DEXA scan may be necessary to assess adequate bone stock.
- **Females of child-bearing age due to unknown effect on the fetus of metal ion release**
- **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)**

### Indications for Use

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 epilateral hip joint revision.

### Contraindications

- **Patients on medications (such as high-dose or chronic amnoglycoside treatment) or with comorbidities (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.**
- **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, Inc. for the surgical technique manual and procedural training protocol.**
- **Currently, Smith & Nephew, Inc. does not have a commercially available metal femoral head component and stem (monoblock or modular) for use with a BHR resurfacing cup (one-piece or modular). Therefore, if the BHR resurfacing head must be revised to a total hip arthroplasty, the one-piece BHR acetabular cup must be revised, even if well-fixed, however, in the case of a modular cup, the R3 Acetabular Shell can remain in place if well-fixed, and the R3 Metal Liner must be replaced with an R3 Poly Liner, which can be used with any compatible legally marketed Smith & Nephew femoral stem and mating ceramic or metal femoral head component.**
- **Based on literature reports1,2, and the clinical study, the following were identified as risk factors for revision. Patients who are female, who receive a smaller component size (<44mm), have the device implanted at a high abduction angle, are obese, or, who have a diagnosis of avascular necrosis have a greater risk of revision than other patients. The more risk factors a patient has, the greater the risk of procedure failure requiring a revision to 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, hemiresurfacing, 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.**

### 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, Inc.**
- **Avoid notchting 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 modular cup, the R3 Acetabular Shell must be used only with an R3 Metal Liner and BHR Femoral Head. However, if the surgeon abandons the BHR resurfacing procedure in favor of a total hip replacement, then the R3 Acetabular Shell must be used in conjunction with an R3 Poly Liner.**

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**Table 1: BHR Head and One-Piece Cup Sizing and System Compatibility**

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
</tr>
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<tbody>
<tr>
<td>Femoral heads, R3 Metal Liners</td>
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<tr>
<td>One-piece BHR Acetabular Cups</td>
<td>cobalt chrome alloy per ASTM F75 and ISO 5832-4; HA coating per ASTM F 1185</td>
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<td>Acetabular screws, screw hole plugs, apex hole plugs</td>
<td>Ti6AlV alloy per ASTM F-1472 and ISO 5832-3</td>
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**Table 2: BHR Head and Modular Cup Sizing and System Compatibility**

<table>
<thead>
<tr>
<th>BHR Femoral Head Resurfacing Component (identified by head outer diameter)</th>
<th>Mating R3 Metal Liner (identified by bearing surface diameter)</th>
<th>Mating R3 Acetabular Shell</th>
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**INDICATION FOR USE**

The 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.
- 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 epilateral hip joint revision.

**CONTRAINdications**

- 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 osteoporosis should not receive a BHR procedure. 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 should not receive a BHR.
  - Patients with multiple cysts of the femoral head (>1cm) should not receive a BHR.
  - Note: In cases of questionable bone stock, a DEXA scan may be necessary to assess adequate bone stock.
- Females of child-bearing age due to unknown effect on the fetus of metal ion release
- 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)
with a mating R3 Poly Liner and any compatible legally marketed Smith & Nephew femoral stem and mating select, or metal femoral head component.

- When performing a hip resurfacing procedure with the one-piece BHR acetal copolymer 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 one-piece 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.
- Instrument 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 tools 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.
- Before impacting the R3 Metal Liner, make sure that it is oriented properly. Perform a visual check to see that the hard bearing alignment guide instrument is sitting on the shell face, and manipulate with fingers to check that the ring does not rock on the face of the shell. Do not impact the liner if it is not oriented properly, as this will damage the shell and/or lock the liner in the shell.
- 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 Acetalcopolymer Implants
- Do NOT allow the HA-coated, porous-surfaced acetalcopolymer 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

A complete list of the complications and adverse events identified in the case series review is provided in Summary of Clinical Studies, Table 15.

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
  - 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 postoperative 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
  - Lumbar discomfort
  - 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 intraoperatively or post-operatively as a result of trauma, excessive loading, malalignment, or osteoporosis
  - Periarticular calcification or ossification
  - Wear or deformation of the articular surface as a result of excessive loading or implant malalignment
  - Disassembly of modular components
  - 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.
Additional Data Sources

In addition to the clinical data series cohorts, less complete data was provided on 3,374 BHR cases performed by 140 surgeons worldwide (other than the single investigator). The follow-up for these cases was also contracted to the Oswestry Outcomes Centre and includes primarily the same parameters as the follow-up for the X-ray/Oswestry combined cohort (adverse events, revisions, deaths, pain and function (OSHP) scores, and patient satisfaction). The Oswestry Outcomes Centre, therefore, collected data on a total of 5,000 BHR cases. These 5,000 cases are referred to as the Oswestry Worldwide Cohort. The Oswestry Worldwide Cohort consists of: 1) the 1,626 cases of the X-ray/Oswestry cohort (the single investigator), and 2) an additional 3,374 non-McMinn (“all other”) cases. The Oswestry Outcomes Centre has provided access to all available data for the BHR cases from its database. Although the data from the 3,374 “all other” cohort was of some value, Smith and Neophy, Inc and FDA have no ability to independently verify any of the data provided to the Oswestry Outcomes Centre by sites other than the McMinn Center, and have no ability to request additional follow-up or clarifications of any kind from non-McMinn patients or physicians. For these reasons, the analysis on the Oswestry Outcomes Centre worldwide database has some limitations, and is not considered the primary data source.

Several literature references were also included which describe the use of over 3,800 BHR devices implanted by multiple surgeons in several countries around the world. One example is the literature reference by Shimmin and Back (Shimmin AJ, Back D. “Femoral neck fractures following Birmingham hip resurfacing: A national review of 50 cases.” J Bone Joint Surg (Br) 87-B:463-4, 2005) which was used in the development of the labeling.

Data Collection Methods

Safety Data Collection Methods

The safety data including adverse events, revisions, and deaths were collected by:

• The Oswestry Outcomes Center using an annual, patient-completed, mail-in questionnaire (ideally) were identified while attempting to perform scheduled follow-up,
• The McMinn Center by recording the findings of postoperative patient visits to the McMinn Center in patient records; and
• Recording information provided to Mr. McMinn by primary care physicians.

Also, a 100% audit of all 2,385 procedures in the Overall McMinn Cohort was performed.

Effectiveness Data Collection Methods

Survivorship Data Collection Method

The primary effectiveness measurement was the X-ray/Oswestry combined cohort survivorship study that included 1,626 procedures performed from July 1997 through March 2002 at the Birmingham Nuffield Hospital. These procedures were a minimum of 2 years postop. Of the 1,626 procedures, data are available for 546 of the 601 BHR procedures eligible for 5-year follow-up (90.8%). The data for the survivorship study was collected using the same methods presented above for the safety data collection methods.

Radiographic Data Collection Method

The clinical data used to support this series contained the results of an independent radiographic review of the X-ray/Oswestry combined cohort survivorship study that included 16/26 procedures performed from July 1997 through March 2002 at the Birmingham Nuffield Hospital. These procedures were a minimum of 2 years postop. Of the 1,626 procedures, data are available for 546 of the 601 BHR procedures eligible for 5-year follow-up (90.8%). The data for the radiographic evaluation was not provided for the 1,502 procedures in the X-ray/Oswestry combined cohort or the 759 procedures in the McMinn Cohort.

The radiographs were interpreted by an independent radiologist. A prospective protocol was developed and used to assess the radiographs. The 5-year AP and lateral view radiographs were compared with the baseline radiographs for the medial-lateral migration, acetabular orientation (tilt angle), femoral and acetabular radiolucentis, heterotopic ossification (HO), bone resorption, acetabular protrusion, cysts, buttressing, and other abnormalities. Radiolucency was defined as a lucent area compared with the baseline radiographs for the medial-lateral migration, acetabular orientation (tilt angle), femoral and acetabular radiolucentis, heterotopic ossification (HO), bone resorption, acetabular protrusion, cysts, buttressing, and other abnormalities. Radiolucency was defined as a lucent area compared with the baseline radiographs for the medial-lateral migration, acetabular orientation (tilt angle), femoral and acetabular radiolucentis, heterotopic ossification (HO), bone resorption, acetabular protrusion, cysts, buttressing, and other abnormalities.

A radiographic success was defined as having all of the following:

• Absence of radiolucentis or a radiolucency in any one or two zones (a score of 0-6),
• Component migration ≤ 2mm, and
• Change in acetabular angle ≤ 5°

A radiographic failure was defined as the following:

• Presence of incomplete or complete radiolucentis or a radiolucency in all zones (a score of 7 or 8),
• A migration of the component > 2mm, or
• A change in acetabular orientation of ≥ 5°

The individual success criterion was the absence of radiographic findings that suggest revision is necessary.

Oswestry-Modified Harris Hip (OSHP) Score Data Collection Method

The clinical data used to support this series were collected by the Oswestry Outcomes Center (OOC) using an annual, patient-completed, mail-in questionnaire. The responses to the pain, function, and movement questions in the questionnaire were used to generate the Oswestry-modified Harris Hip (OSHP) Score.

The main difference between the OSHP questionnaire and the HHS is that the OSHP allows patient assessments without direct physician or examiner evaluation. In addition, the OSHP questionnaire does not include the three HHS questions regarding physician assessment of Range of Motion (5 pts.), Absence of Deformity (4 pts.), and the patient’s ability to put on socks or shoes (4 pts.) but substitutes a “movement” question (3 pts.) that is intended for the patient to estimate their ability to flex their hip.

Patient Satisfaction Data Collection Method

Patient satisfaction data was also collected using the annual, patient-completed, mail-in questionnaire. For the purpose of the BHR study, an additional question about patient satisfaction was appended to the end of the OSHP assessment questionnaire.

Literature References

A literature search was performed to find published studies of ceramic-on-ceramic total hip replacements to provide a comparison for the BHR clinical study data. The following two articles were identified:


The data in these references have some differences as compared to the data provided for the BHR device in this clinical data series, including:

• Different evaluations, (OSHP for BHR and HHS for literature)
• Length of follow-up (18-36mo and 2-4 years for the controls and 2-5 years for the BHR study)
• Mean baseline pain and function scores (e.g.; 60 for OSHP in BHR Oswestry cohort, 44 for HHS
• Garino study, and not reported for O’Doherty study)

• Indications for use, (including differences in the rate of displasia and AVN diagnostic indications)

However, the literature information provided valuable information on approved ceramic-on-ceramic total hip replacement (THRs) systems for comparison purposes including patient demographics, diagnostic indications, patient accounting, adverse events, revision rates, pain, function, and radiographic results. This information is summarized in sections below for reference purposes.

PATIENT DEMOGRAPHICS

Demographics for X-Ray, Oswestry, McMinn, and Overall McMinn cohorts

Patients in the Overall McMinn cohort were 70.6% men and 29.4% women, ages 13-86 years (average 53.1 years). The primary diagnosis was osteoarthritis in 75.0%, dysplasia in 15.8%, avascular necrosis in 4.1%, inflammatory arthritis in 2.4%, and “other” in 2.7% (Table 5).

Demographics for X-Ray/Oswestry combined cohort

One thousand and one hundred and eleven (1,111) of the X-ray/Oswestry combined cohort cases (68%) were unilateral procedures and 515 (32%) were bilateral procedures. The indication for the majority of cases was osteoarthritis. Table 6 provides the breakdown of unilateral and bilateral cases by indication.

Some of the patients with bilateral hip replacements were included in different groups depending on when the second hip procedure was performed (Table 7).

Table 6: Diagnostic indication for BHR

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Unilateral</th>
<th>Bilateral</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis</td>
<td>849 (78.4%)</td>
<td>144 (14.5%)</td>
<td>676 (77.7%)</td>
</tr>
<tr>
<td>Displasia</td>
<td>69 (6.4%)</td>
<td>59 (5.5%)</td>
<td>128 (14.5%)</td>
</tr>
<tr>
<td>Avascular necrosis</td>
<td>32 (2.9%)</td>
<td>14 (1.4%)</td>
<td>46 (2.5%)</td>
</tr>
<tr>
<td>Inflammatory arthritis</td>
<td>13 (1.2%)</td>
<td>10 (1.0%)</td>
<td>23 (2.5%)</td>
</tr>
<tr>
<td>Other</td>
<td>62 (5.6%)</td>
<td>64 (5.9%)</td>
<td>126 (13.5%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1091 (97.1%)</td>
<td>102 (10.1%)</td>
<td>1193 (100%)</td>
</tr>
</tbody>
</table>

Table 7: Hip Procedures

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Patients</th>
<th>Hips</th>
<th>Unilateral</th>
<th>Bilateral</th>
<th>Coronal/femoral Single Hip Cohort</th>
<th>X-Ray</th>
<th>Oswestry</th>
<th>McMinn</th>
<th>Singles</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-Ray</td>
<td>119</td>
<td>568</td>
<td>547</td>
<td>11</td>
<td>12 (15.8%)</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Oswestry</td>
<td>130</td>
<td>650</td>
<td>543</td>
<td>102</td>
<td>202 (61.1%)</td>
<td>11</td>
<td>22</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>McMinn</td>
<td>685</td>
<td>1568</td>
<td>1502</td>
<td>66</td>
<td>110 (94.6%)</td>
<td>8</td>
<td>3</td>
<td>12</td>
<td>49</td>
</tr>
</tbody>
</table>

* Patients with bilateral hip replacements with the coronal/femoral hip included in the first hip replacement's evaluation cohort
** Number of patients equals unilateral + bilateral + singles
*** Number of hips equals unilateral + (2 x bilateral) + singles
Demographics: Literature References
The study published by D’Antonio et al. reported findings from a multicenter study conducted at 22 investigational sites, the study published by Garino was conducted at 11 investigational sites (Table 8).

Table 9: Indications for Use for Literature References

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>D’Antonio et al</th>
<th>Garino JP</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSTEARTHritis</td>
<td>399</td>
<td>333</td>
</tr>
<tr>
<td>TRAUMATIC OSTEARTHritis</td>
<td>21</td>
<td>32</td>
</tr>
<tr>
<td>AVASCULAR NECROSIS</td>
<td>82</td>
<td></td>
</tr>
<tr>
<td>OTHER / NOT REPORTED</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>334</td>
<td></td>
</tr>
</tbody>
</table>

Patient Accounting
The follow-up rates for the Combined X-Ray/Oswestry Cohort, upon which the effectiveness analyses were performed, at the 1-year, 2-year, 3-year, 4-year, and 5-year postoperative evaluation time points were 76.6%, 77.3%, 88.1%, 88.6%, and 90.8%, respectively. There were 546 procedures (hips) evaluated at 5 years in this cohort (Table 10).

Table 10 Patient Accounting Based on the number of procedures

<table>
<thead>
<tr>
<th>Baseline</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounting for Survivorship (% Revision Free)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X-Ray</td>
<td>-</td>
<td>124 (1.0)</td>
<td>123 (0.8)</td>
<td>123 (0.6)</td>
<td>122 (1.0)</td>
</tr>
<tr>
<td>Oswestry</td>
<td>-</td>
<td>152 (6.3)</td>
<td>150 (4.9)</td>
<td>137 (5.2)</td>
<td>116 (3.3)</td>
</tr>
<tr>
<td>McMinn</td>
<td>-</td>
<td>79 (3.20)</td>
<td>446 (0.379)</td>
<td>87 (0.41)</td>
<td>3 (0.10)</td>
</tr>
</tbody>
</table>

- **X-Ray Cohort**
  - Expected: 124
  - Evaluated: 82
  - FU %: 51%
  - FU %: 100%

- **Oswestry Cohort**
  - Expected: 152
  - Evaluated: 122
  - FU %: 77%

- **McMinn Cohort**
  - Expected: 79
  - Evaluated: 3

X-Ray / Oswestry Combined Cohort

<table>
<thead>
<tr>
<th>Theoretical</th>
<th>1626</th>
<th>1362</th>
<th>1053</th>
<th>1103</th>
<th>1103</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths (procedures)</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Revisions (cumulative)</td>
<td>0</td>
<td>10</td>
<td>20</td>
<td>21</td>
<td>23</td>
</tr>
</tbody>
</table>

- **Overall McMinn Cohort**
  - Number of procedures: 2385
  - Revisions: 83

Summary of the Oswestry and X-Ray Cohorts - Unilateral Based on Available OSHIP Data

Table 11: Patient Accounting Summary of the Oswestry and X-Ray Cohorts - Unilateral Based on Available OSHIP Data

<table>
<thead>
<tr>
<th>Baseline</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>165 control THR procedures (161 patients), 349 ceramic-on-ceramic THR procedures (318 patients)</td>
<td>165 control THR procedures (161 patients), 349 ceramic-on-ceramic THR procedures (318 patients)</td>
<td>165 control THR procedures (161 patients), 349 ceramic-on-ceramic THR procedures (318 patients)</td>
<td>165 control THR procedures (161 patients), 349 ceramic-on-ceramic THR procedures (318 patients)</td>
<td>165 control THR procedures (161 patients), 349 ceramic-on-ceramic THR procedures (318 patients)</td>
<td>165 control THR procedures (161 patients), 349 ceramic-on-ceramic THR procedures (318 patients)</td>
</tr>
</tbody>
</table>

SAFETY DATA

Safety: Revisions
There were 27 procedures that required revision. Two of the 27 revisions occurred beyond the 5-year follow-up time point in the X-Ray cohort (Table 13).

Table 13: Revisions Stratified by Cohort

<table>
<thead>
<tr>
<th>Number of procedures</th>
<th>X-Ray Cohort N = 124</th>
<th>Oswestry Cohort N = 1502</th>
<th>McMinn Cohort N = 2385</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revisions</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>

Safety: Revisions Comparison with Literature References
A comparison of the revision rates between the BHR study cohorts and the two literature reference groups was provided. The revision rate for the primary efficacy cohort was 1.47% at 5 years compared to 1% for 5, 2.1%, and 1.2%, respectively, for the D’Antonio ceramic-ceramic, D’Antonio metal-poly, and Garino literature reference groups (Table 14).

Table 14: Revision Rate Comparisons

<table>
<thead>
<tr>
<th>Cohort</th>
<th>X-Ray</th>
<th>Oswestry</th>
<th>X-Ray / Oswestry Combined</th>
<th>McMinn</th>
<th>Overall McMinn</th>
<th>D’Antonio Ceramic-Ceramic</th>
<th>D’Antonio Metal-Poly</th>
<th>Garino</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>524</td>
<td>500</td>
<td>1626</td>
<td>2385</td>
<td>2385</td>
<td>338</td>
<td>338</td>
<td>333</td>
</tr>
<tr>
<td>Revisions</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Rate %</td>
<td>3.2%</td>
<td>1.0%</td>
<td>1.9%</td>
<td>1.3%</td>
<td>1.3%</td>
<td>1.3%</td>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Years</td>
<td>5</td>
<td>4.5</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

* The number of procedures is the number of hips that were surviving at the end of the previous year based on the survival analysis. Not all of the X-Ray data is starting from day 1 and the “year 2” data is starting from day 366, etc.

There were 10 revisions due to a femoral neck fracture, 6 for femoral head collapse, 1 for dislocation, 2 for AVN (1 led to femoral head collapse and 1 led to a femoral neck fracture), and 8 for infections (2 led to head collapse, 1 led to a femoral neck fracture). Altogether, there were 12 femoral neck fractures that required revisions. Factors that may have contributed to the femoral neck fractures include age-related osteopenia (2 patients), poor preoperative bone quality as evidenced by cysts in the femoral head and acetabulum, and smaller femoral head size (1 case), infection that led to bone death (1 case), femoral head cysts (1 case), and malpositioned component (1 case). The 9 cases with femoral head collapse (6 primary femoral head collapses, 2 collapses due to infection and 1 due to AVN) Factors that may have contributed to the femoral head fractures include infection (2 cases), AVN (2 cases), femoral head cysts and soft bone (3 cases), osteopenia (1 case), and unknown.

Safety: Revisions Comparison with Literature References
The safety and effectiveness of the hip resurfacing procedure was evaluated through a comparison of the revision rates between the BHR study cohorts and the two literature reference groups. The revision rate for the primary efficacy cohort was 1.47% at 5 years compared to 1% for 5, 2.1%, and 1.2%, respectively, for the D’Antonio ceramic-ceramic, D’Antonio metal-poly, and Garino literature reference groups (Table 14).
and 9 “resolved with antibiotics.” There were two patients who were revised for other indications (component migration and femoral neck fracture) who were found to be infected.

Safety: Adverse Events - Deaths
There were 20 patient deaths (26 procedures) in the Overall McMinn Cohort. It was determined in no case was a death related to the BHR procedure. The causes were reported to be: 3 stroke, 4 cancer, 1 motor neuron disease, 1 esophageal cancer and pneumonia, 1 myocardial infarction, 1 suicide, 1 ruptured aorta, 1 carcinoma prostate with metastases, 1 unconfirmed – either diving accident or myocardial infarction, 7 unreported.

Safety: Metal Ion Literature Analysis
Literature references were provided to address concerns for metal ion release. An unpublished report by Daniel J, Ziaee H, and McMinn D, entitled, “Metal ion studies in patients treated with the Birmingham Hip Resurfacing, a comparable FDA-approved device and historic metal-metal total hip replacements” was provided. The authors conducted 4 metal ion studies in patients who received BHR, Metal-metal total hip replacements, and other marketed (historic) metal-metal total hip replacements. In addition, a summary of literature references pertaining to the medium and long-term safety of cobalt and chromium ion exposure was provided.

The unpublished and published literature demonstrate that serum and urinary metal ion concentrations in patients with total hip replacement in general, and metal-metal implants in particular, is increased in the postoperative period. However, there does not appear to be any conclusive evidence that elevated chromium and lead levels have any significant detrimental effects in total hip arthroplasty patients.

<table>
<thead>
<tr>
<th>Table 15: Adverse Events - Overall McMinn Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse Event</strong></td>
</tr>
<tr>
<td>Number of procedures</td>
</tr>
<tr>
<td>Procedures with AL (%)</td>
</tr>
<tr>
<td>AL% femoral head/neck</td>
</tr>
<tr>
<td>Femoral head collapse</td>
</tr>
<tr>
<td>Component migration/mothing</td>
</tr>
<tr>
<td>Femoral neck fracture</td>
</tr>
<tr>
<td>Infection (device related)</td>
</tr>
<tr>
<td>Dislocation</td>
</tr>
<tr>
<td>Cardiac event</td>
</tr>
<tr>
<td>Infusion</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Reaction at incision site</td>
</tr>
<tr>
<td>Event at implant site (surgery)</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Thromboembolic event</td>
</tr>
<tr>
<td>Pain</td>
</tr>
<tr>
<td>Deep Venous Thrombosis</td>
</tr>
<tr>
<td>Infection (hip procedure related)</td>
</tr>
<tr>
<td>Neumonias</td>
</tr>
<tr>
<td>Fever</td>
</tr>
<tr>
<td>A-X ray report comment</td>
</tr>
<tr>
<td>Osteoporosis, weakness, flexion deformity, restricted ROM</td>
</tr>
<tr>
<td>Urinary</td>
</tr>
<tr>
<td>Wound exposure</td>
</tr>
</tbody>
</table>

*Time course of events shows the number and % of subjects with at least 1 complication of the specified type in the specified time period. Subjects may appear in more than one time period. Events without time information were not included in the table.

**EFFECTIVENESS DATA**
Survivorship
The survivorship estimates were based on the number of patients with no revision. Survivorship analyses were provided for various cohorts and demographic subgroups calculated according to Peto’s adjustment method as follows (Table 16).

**Table 16: % Survivorship Analyses (no revision)**

<table>
<thead>
<tr>
<th>Population</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray Cohort</td>
<td>99.2</td>
<td>98.2</td>
<td>98.4</td>
<td>98.4</td>
<td>98.4</td>
</tr>
<tr>
<td>Oswestry Cohort</td>
<td>99.1</td>
<td>98.9</td>
<td>98.8</td>
<td>98.8</td>
<td>98.8</td>
</tr>
<tr>
<td>X-ray + Oswestry Combined Cohort</td>
<td>99.0</td>
<td>98.6</td>
<td>98.6</td>
<td>98.6</td>
<td>98.6</td>
</tr>
<tr>
<td>McMinn Cohort</td>
<td>99.0</td>
<td>98.7</td>
<td>98.8</td>
<td>98.8</td>
<td>98.8</td>
</tr>
<tr>
<td>Overall McMinn Cohort</td>
<td>99.0</td>
<td>98.7</td>
<td>98.8</td>
<td>98.8</td>
<td>98.8</td>
</tr>
</tbody>
</table>

Due to small number of revisions (total 25, ≤5 year follow-up) from large numbers in three study cohorts (total of 2,385 hips), there were no statistically significant differences for all pairwise comparisons in 5-year survival (revision-free) probabilities among three study cohorts. Both Cox PH regression model and the log-rank test require that the two survival probability curves be parallel or nearly parallel (no significant cohort by time crossover).

The above three statistic significance tests were also applied to several clinically important patient covariates, which include age (<65, ≥65), gender (M, F), reason for resurfacing (Avascular, OA, IA, dysplasia, and others, reference group = OA), baseline OSHIP score (yes, no), hips unilateral, bilateral. The only marginally statistically significant difference in 5-year survival probability was between the patients with Osteoarthritis (98.8%) and Avascular Necrosis (97.1%) as their primary diagnostic indication. The p-values to compare these two % revision-free curves for OA versus AVN comparison are p=0.0415 (Log-rank) and p=0.2282 (Wilcoxon).

**Figure 1. Cumulative % Revision-Free, BHR**

Due to non-parallelism of the Oswestry and X-Ray survival curves, careful clinical interpretation is needed. Both log-rank and Wilcoxon test that the two revision-free curves are equal, and the Cox PH model tests that the ratio of the two hazards (probability of revision) is unity. The log-rank test assigns equal weight to all follow-up times and the Wilcoxon test assigns more weight to the earlier follow-up times where more patients are at risk of revision. The log-rank test has optimal statistical power if the parallelism assumption for the two revision-free curves is valid. The Cox PH model is not appropriate here due to obvious non-parallelism of the two curves in Figure 1. The percentages of
revisions are 3% (3/97) for AVN, 1% for dysplasia (4/377), 0.95% (7/759) for OA, 17% (1/57) for inflammatory arthritis (IA), and 0% for others (0/65), with a combined 1% (25/2,383) revisions over all diagnostic groups, during 5-year follow-up.

Radiographic Data

The clinical data used to support this series contained the results of an independent radiographic review of the X-Ray Cohort, the first 124 procedures performed in the series from July 1997 through December 1997.

Radiographs were taken on 108 of the 118 procedures expected at 5 years postoperatively (95.5%). Six (6) procedures were not expected at 5 years postoperatively because one patient with bilateral hip implants died from a motor neuron disease unrelated to the BHR procedure, and 4 of the 124 BHR procedures (3.2%) have undergone revision. 3 cases were revised for infection, and 1 case required revision because of a femoral neck fracture. Therefore, 118 procedures (124 hips - 2 hips due to death - 4 revisions = 118 procedures) were eligible for 5 year radiographic evaluation of the BHR. Ten other cases were missing due to lost to follow-up or incomplete film records. Therefore, one hundred and (100) of the 118 hips surviving to 5 years had 5-year radiographs available for independent review (91.5%). (Note: An additional bilateral patient died 7 years post-op due to stroke but had 5 year x-rays taken).

Baseline films for the purposes of comparisons were made in each of the 108 cases in the postoperative time period usually within 3 months, but 8 of the 108 procedures had baseline evaluations performed at time points ranging from 110-860 days.

Radiographic Study: 5-Year Radiographic Assessments

The radiographs were assessed for radiolucencies, bone resorption, heterotopic bone, acetabular angle, medial/lateral migration, and other observations to determine whether a revision surgery was necessary.

Femoral radiolucencies: Radiolucencies were graded 0-9 (Amstutz scale). There were femoral radiolucencies found in 4 cases (4%), one each with grade 9 migration, grade 5 (zone 2-3), grade 2 (zone 1) and grade 1 (zone 2). The patient with a grade 9 femoral radiolucency was classified as a radiographic failure.

Acetabular radiolucency: Radiolucencies were graded 0-9 (DeLee and Charnley scale). There were 21 hips with acetabular radiolucencies, both with grade 8 (zones I-III, complete) findings. One hip had preoperative acetabular cysts that progressed over time, and the other had a preoperative dysplastic acetabulum and developed protrusio. Both were classified as radiographic failures. Three patients had insignificant radiolucencies (grade 1 in two hips and grade 2 in one hip).

Heterotopic bone: There were 21 hips that had Brooker I and 5 hips with Brooker II heterotopic ossification (HO). Only 2 hips had "clinically significant HO," i.e., Brooker III or IV. Both had Brooker III HO. Thus, 28 of the 108 procedures evaluated (28%) had any heterotopic bone at 5 years and 27% had significant HO. None of the cases with heterotopic bone were determined to require a revision.

Acetabular angle: There was only one case that had a change in the acetabular angle >5°. This patient also had the grade 8 acetabular radiolucency (see above). No cases had a change in acetabular angle that was determined to be an indication for a revision.

Medial / Lateral Migration: There were no procedures with a change in medial/lateral acetabular cup position, and no cases with a change in acetabular position that was determined to be an indication for a revision.

Additional observations: Bone resorption at the femoral neck was found in 3 cases. In no case was the resorption associated with any other notable radiographic findings. Bone cysts were found in 2 patients: one, described above, and the other had 3cm cysts associated with a grade 1 acetabular radiolucency. No other significant signs were noted.

Three (3) of the 108 (2.8%) patients for whom radiographs were available were radiographic failures at 5 years (Table 17).
For the data in the table above regarding the number of procedures who improved ≥ 10 pts., maintained, or deteriorated ≥ 10 pts., that those patients with no baseline scores were counted as “maintained.” The table below contains an analysis of the number of procedures who improved ≥ 10 pts., maintained, or deteriorated ≥ 10 pts., when the patients without baseline scores were removed from this analysis and just counted as missing (Table 20).

### Table 20: OSHP Improvement Oswestry & X-Ray Cohorts

<table>
<thead>
<tr>
<th>Change</th>
<th>Year</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5+ Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral</td>
<td></td>
<td>192/3</td>
<td>168/3</td>
<td>162/3</td>
<td>162/3</td>
<td>162/3</td>
</tr>
<tr>
<td>Same &lt;10</td>
<td></td>
<td>91</td>
<td>84</td>
<td>85</td>
<td>90</td>
<td>94</td>
</tr>
<tr>
<td>Worse ≥10</td>
<td></td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td>715</td>
<td>550</td>
<td>633</td>
<td>644</td>
<td>602</td>
</tr>
<tr>
<td>Missing</td>
<td></td>
<td>386</td>
<td>99</td>
<td>249</td>
<td>239</td>
<td>92</td>
</tr>
</tbody>
</table>

Pain and Function - Comparison to Literature References

In the literature references, the authors used Harris Hip Score, not OSHP, to collect pain and function effectiveness data. D’Antonio et al. reported Harris Hip Scores at 2 - 4 year follow up (mean 3 year) for the ceramic-on-ceramic hip procedures as follows:

- **ABC System 1 (porous):** 95.4 mean score (n=166)
- **ABC System 2 (HA):** 96.6 mean score (n=172)

Garnino reported an average increase in Harris Hip Score 4 pre-operatively to a mean of 97 at follow up.

Patient Satisfaction

The patient satisfaction question is not a standard component of the OSHP assessment but was an additional question asked for this study in the annual, patient-completed, mail in questionnaire. At 5 years, 95.5% of the procedures in the X-Ray/Oswestry combined cohort were pleased or very pleased with the operation. At 4 years, 99.2% of the unilateral procedures from the X-Ray/Oswestry combined cohort were pleased or very pleased with the operation (Table 21).

### Table 21: Patient Satisfaction X-Ray / Oswestry Combined Cohort

<table>
<thead>
<tr>
<th>Assessment</th>
<th>X-Ray / Oswestry Combined Cohort N = 1626</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base</td>
<td>N</td>
</tr>
<tr>
<td>Pleased</td>
<td></td>
</tr>
<tr>
<td>Satisfied</td>
<td></td>
</tr>
<tr>
<td>Very pleased</td>
<td></td>
</tr>
</tbody>
</table>

Additional Data Sources

The main data sources were presented above but additional, less complete data on 3,374 BHR™ cases, performed by 140 surgeons worldwide (other than the single investigator) was summarized. This is the Worldwide/Other Cohort.

Demographic information for the Worldwide/Other Cohort included gender, age, diagnosis, BMI, baseline OSHP scores. The study cohort demographics was similar in the Worldwide/Other Cohort and the X-Ray/Oswestry combined cohort, with the mean age of 53.0 years in the X-Ray/Oswestry combined cohort and 52.5 years in the Worldwide/Other Cohort. The diagnostic indications were somewhat different between cohorts: OA (78% X-Ray/Oswestry combined cohort vs. 90.8% Worldwide/Other Cohort).

A comparison of the revisions and survivorship estimates for the X-ray/Oswestry combined cohort versus the Worldwide/Other Cohort was provided. The primary reason for revision in the Worldwide/Other Cohort was a fracture in 34 cases (1.0%), loosening in 26 cases (0.8%), infection in 7 cases, AVN in 5 cases, dislocation in 5 cases, miscellaneous device failures in 5 cases, pain in 3 cases, and unknown in 3 cases (Table 22).

### Table 22: Revisions

<table>
<thead>
<tr>
<th>X-Ray / Oswestry Combined Cohort N = 1626</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of procedures</td>
</tr>
<tr>
<td>Revision</td>
</tr>
<tr>
<td>Survivorship estimates</td>
</tr>
<tr>
<td>Worldwide / Other Cohort N = 3374</td>
</tr>
<tr>
<td>Number of procedures</td>
</tr>
<tr>
<td>Revision</td>
</tr>
<tr>
<td>Survivorship estimates</td>
</tr>
</tbody>
</table>

### Table 23: OSHP - Worldwide / Other Cohort

<table>
<thead>
<tr>
<th>Baseline</th>
<th>2 Years</th>
<th>3 Years</th>
<th>4 Years</th>
<th>5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worldwide</td>
<td>1626</td>
<td>1457</td>
<td>1379</td>
<td>505</td>
</tr>
<tr>
<td>Worldwide Mean</td>
<td>1626</td>
<td>91.67</td>
<td>91.47</td>
<td>91.45</td>
</tr>
</tbody>
</table>

**STERILIZATION**

- **Implant components are sterilized to a Sterility Assurance Level (SAL) of 10^-6.** Metal components are sterilized to a minimum of 25 kilosRays 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 (0.8 bars) & Minimum = 10.0 inHg (0.39 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
  - **Vacuum Flash Cycle:** 4 pulses (Maximum = 26.0 psig (0.8 bars) & Minimum = 10.0 inHg (0.39 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, Inc. Sales Representative regarding procedures to return components.**

The product is not labeled “pyrogen free”.

The BHR™ Femoral head and BHR™ one-piece acetabular shell components are packaged in a Tyvek™ vacuum peel pouch to maintain sterility. The products have a five (5) year sterile shelf-life.

The R3™ Acetabular Shells and R3 Metal Liners are packaged with a dual sterile barrier to maintain sterility. The products have a ten (10) year sterile shelf life.

**MAGNETIC RESONANCE IMAGING (MRI) SAFETY**

The BIRMINGHAM HIP Resurfacing (BHR) System has not been evaluated for safety and compatibility in the MR environment. The BIRMINGHAM HIP Resurfacing (BHR) System has not been tested for heating or migration in the MR environment.

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

**INFORMATION**

For further information, please contact Smith & Nephew, Inc. Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

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8106226 Rev. C 10/10

References:
2. Oliver, B. et al., JBJS 2010. 91-B(No. 8): p.1025-30