

**Device Description**

The BIRMINGHAM HIP™ Resurfacing (BHR) prosthesis is a metal-on-metal hip *resurfacing* prosthesis, meaning that it does not remove the natural femoral head. The device consists of a stemmed femoral head resurfacing component designed for cemented fixation, and a hemispherical acetabular cup designed for cementless fixation. The acetabular cup has an integrally cast porous outer surface coated with hydroxyapatite to support bone ingrowth. Bridging cups, acetabular cups configured for dysplasia indications and dysplasia screws are also available. Instrumentation sets are provided as standard; several additional instruments are available as options.

**Materials**

System Component	Materials and Standards
Femoral Head Resurfacing Component	High-carbon cobalt chrome per: ASTM F75, and ISO 5832 Part 4
Acetabular Cup Component	High carbon cobalt chrome per: ASTM F75, and ISO 5832 Part 4  Hydroxyapatite powder per: ASTM F-1185

**Sizing and System Compatibility**

Each femoral head resurfacing component is compatible with two standard acetabular cup sizes and one Dysplasia or Bridging cup size as shown below.

BHR Femoral Head Resurfacing Component (by head outer diameter)	Mating BHR Cup Sizes (2 per head component size)	Mating BHR Dysplasia Cup Sizes	Mating BHR Bridging Cup Sizes
38mm	44mm or 46mm	46mm	50mm
42mm	48mm or 50mm	50mm	54mm
46mm	52mm or 54mm	54mm	58mm
50mm	56mm or 58mm	58mm	62mm
54mm	60mm or 62mm	62mm	66mm
58mm	64mm or 66mm	66mm	

**Indications 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 patients who are undergoing hip resurfacing arthroplasty to relieve hip pain and improve hip function in hips damaged by:

- Non-inflammatory degenerative joint diseases such as osteoarthritis,
- Avascular necrosis,
- Dysplasia/DDH, and
- Inflammatory degenerative joint disease such as rheumatoid arthritis.

Hip resurfacing arthroplasty is intended as a primary joint replacement for patients who are at risk of requiring more than one hip joint replacement over their lifetimes. While it is

impossible to predict which patients will require more than one joint replacement, factors that are known to increase risk for revision surgery include age <55 at initial surgery or high activity level.

### **Contraindications**

The BHR system is contraindicated in:

- 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.
  - Patients with severe osteopenia should not receive a BHR procedure. Patients with a family history of osteoporosis or severe osteopenia, and peri- and postmenopausal women are at increased risk for 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.
- Women of child-bearing age due to unknown effect of metal ion release,
- Patients with known renal failure

### **Warnings**

- Do NOT use any component of the BHR system with another manufacturer's implant components, because designs and tolerances may be incompatible. Smith & Nephew accepts no responsibility for BHR system components that have been used with another manufacturer's system components.
- Do NOT use BHR system components (which are cobalt chrome) with any stainless steel components, because corrosion can occur using these dissimilar metals.
- Do NOT allow hydroxyapatite-coated surfaces to contact any substance other than the device packaging, clean gloves, or the patient's tissue.
- Previous hip surgery such as failed osteotomies, failed core decompressions, failed hemiresurfacing, and failed internal fixation may increase the risk of early failure.
- 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.
- Do NOT re-use an implant. All implants are intended for single-use only.

### **Precautions**

- Use the recommended instruments and the recommended surgical technique.
- Excessive activity levels, excessive patient weight, and trauma to the joint replacement may cause premature 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.
- 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 can also cause excessive wear and early failure.

**Potential Adverse Effects on Health**

The following adverse effects may occur in association with artificial hip replacement surgery:

- Cardiovascular complications including venous thrombosis, pulmonary embolism, or myocardial infarction,
- A sudden drop in blood pressure intra-operatively due to the use of bone cement,
- Hematoma or damage to blood vessels,
- Delayed wound healing,
- Infection,
- Temporary or permanent nerve damage resulting in pain or numbness to the affected limb,
- Metal sensitivity reactions or allergic reactions,,
- 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),
- Fatigue fracture of the implants (as a result of excessive loading, malalignment, or trauma),
- Metallosis and osteolysis,
- Bone perforation or fracture (occurring either intra-operatively, or occurring 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).

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

**Clinical Data – Safety Information**

A clinical study was performed to evaluate the complications and revisions associated with 2,385 BHR cases with an average follow-up of 3 years. Table 1 shows the demographics of the study population. Table 2 shows the complications that occurred over time. Revisions occurred in 27 cases (1%).Table 3 shows revisions over time.

Table 1: Demographics

Study Group	2,385 cases
Gender	
Male	1684 (71%)
Female	702 (29%)
Age in years	
Mean	53
Range	13-86
Pre-op diagnosis	
Osteoarthritis	1789 (75%)
Dysplasia/DDH	377 (16%)
Avascular necrosis	97 (4%)
Inflammatory arthritis	57 (2%)
Other	65 (3%)

Table 2: Complications

<<S&N proposes these categories for the AE table. If FDA agrees with these proposed categories and format, the table will be completed with the occurrences shown in

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statistical table 21.1 of this Amendment for the combined X-ray/Oswestry/McMinn cohorts>>

Visit	BHR (2385 cases)							Total
	Post-op	1	2	3	4	>=5		
N = cases evaluated								
<b>Operative Site Related</b>								
Revision								
AVN								
Femoral Head Collapse								
Component migration/loosening								
Fractured neck of femur								
Heterotopic ossification								
Impingement								
Dislocation								
Late infection								
Post-op infection								
Pain								
Limp								
Stiffness, restricted motion, etc								
Localized event at implant site								
Localized reaction at implant site								
Wound exudate								
Radiological report comments								
Not Applicable								
Other								
<b>Systemic</b>								
Cardiac event								
.Drop in hemoglobin								
Hypotension								
Post-op deep vein thrombosis								
Thromboembolic event								
Post-op pneumonia								
Pyrexia								
UTI								
<b>TOTAL</b>								

Table 3: Revisions

Post-op Year 1	13
Post-op Year 2	5
Post-op Year 3	5
Post-op Year 4	1
Post-op Year 5	1
Post-op Year >5	2
Total Revisions	27

### Effectiveness Information

A clinical study of effectiveness measures was conducted on 1,626 BHR cases with average follow-up of 4 years. (The 1,626 BHR cases are a subset of the population discussed in *Safety Information* above.) Demographics for the 1,626 cases with effectiveness measures are provided in Table 4.

Table 4: Demographics

Study Group	1,626 cases
Gender	
Male	1163 (72%)
Female	463 (28%)
Age in years	
Mean	53
Range	13-87
Pre-op diagnosis	
Osteoarthritis	1263 (78%)
Dysplasia/DDH	219 (13%)
Avascular necrosis	66 (4%)
Inflammatory arthritis	41 (3%)
Other	37 (2%)

The 1,626 BHR cases were given a self-administered Oswestry Hip Score (OSHIP). The OSHIP evaluates pain, function, and movement, and assigns a score from 0-100, with 100 being the best. A score of 80 or better is considered good/excellent. In addition to the OSHIP, patients were asked about their overall satisfaction with their BHR procedures. Table 5 summarizes the OSHIP score results. Table 6 summarizes the patient satisfaction results.

Table 5: OSHIP Scores

	OSHIP result	% of subjects with 80 or better
Mean pre-op score	60	3%
Mean 1-year score	96	97%
Mean 2-year score	97	97%
Mean 3-year score	96	95%
Mean 4-year score	96	96%
Mean 5-year score	95	94%

Table 6: Patient Satisfaction

	% of those who responded pleased or extremely pleased overall
1-year	96
2-year	>99
3-year	>99
4-year	>99
5-year	>99

### **Operating Information**

- The surgeon should be thoroughly familiar with the implants, instruments, and procedure before performing surgery. Contact Smith & Nephew for the surgical technique manual or procedural training.
- 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.
- 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.

### **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 a substitute for cement and is not intended to compensate for inadequate implant fixation.

### **Information for the Patient**

- 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 pre-operative year while the bone is healing.
- Warn the patient that artificial joint replacement devices can wear out over time, and may require replacement.

### **Packaging and Labeling**

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.

### **Sterilization**

Implant components are supplied sterile to a Sterility Assurance Level (SAL) of  $10^{-6}$ . 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

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- 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.

### **Resteralization**

DO NOT RESTERILIZE implant components. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components.

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

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