

BIRMINGHAM HIP[®] Resurfacing (BHR[®]) System

PATIENT INFORMATION

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Glossary of Terms

- Artificial: Man-made.
- Hip Joint: A bone joint made up of a ball head (femoral head) and socket (acetabulum)
- Hip Dislocation: A hip problem resulting from a separation of the ball from the socket in an artificial hip replacement device.
- Migration: A hip complication resulting from a movement of the device out of its original position.
- Degenerative joint disease: A condition that causes the loss of cartilage and bone in a hip joint that eventually leads to increased hip joint pain and reduced hip joint function. Names of some types of degenerative joint diseases include;
 - Hip Dysplasia: An unusually-shaped hip socket.
 - Osteoarthritis: A condition that results in loss of bone and cartilage in the hip joint and/or formation of bone and cartilage in the joint where it normally does not occur (osteophytes).
 - Traumatic arthritis: A condition that results in loss of bone and cartilage in the hip joint after a physical injury to the hip joint has occurred.
 - Avascular Necrosis: Death of the bone in the femoral head due to loss of blood circulation within the bone caused by disease or damage to the hip bone.
 - Rheumatoid arthritis: A condition where the connective tissue (collagen) of the hip joint is slowly destroyed due to the body attacking its own tissue (auto-immune response).
- Femoral Neck Fracture: Breakage of the bone below the hip ball head.
- Femoral Head Collapse: Breakage of the bone within the hip ball head.
- Osteoporosis: A condition resulting in loss of bone that causes bone to become brittle and weak.
- Rehabilitation: After hip surgery, doctor prescribed exercises that help improve hip movement and healing

- Revision: Replacement of an artificial hip device with a new artificial hip device. Revision can be required due to several reasons such as a broken device or infection or incorrect artificial hip device position in the bone.
- Magnetic Resonance Imaging (MRI): A medical imaging technique commonly used in radiology to visualize the internal structure and function of the body.

1.0 What Is the BHR Device?

Your hip is a socket and ball joint where the thighbone and pelvis come together. As your leg moves, the ball of your thighbone (called the femoral head) moves and rotates against the socket portion of your pelvic bone (called the acetabulum). If your hip joint is diseased due to certain kinds of arthritis, or previous damage, it will become less functional and more painful over time. When your hip pain increases to the point that it can not be helped by usual measures such as pain medicine and exercises (physical therapy) and your ability to move your hip decreases, affecting your ability to do your daily activities, it may become necessary to surgically replace the hip joint.

The BIRMINGHAM HIP Resurfacing (BHR) device consists of a socket in the shape of a shallow cup (acetabular component), and a cap in the form of a ball head (femoral resurfacing component). See Figures 1a and 1b.

- The cup replaces the damaged surface of your hip socket (acetabulum).
- The cap covers the ball-shaped bone at the top of your thigh (femoral head), and the cap has a small stem that is inserted into the top of your thighbone.

The cap moves within the cup. The surfaces that rub against each other (the bearing couple) are made from highly-polished metal. This type of bearing couple is called a metal-on-metal bearing couple.

The cup (acetabular component) is available in two styles: a one-piece cup (See Figure 1a) or a two-piece cup (See Figure 1b). The one-piece cup is a single component. The two-piece cup has a metal outer shell and a separate metal liner that locks into the shell.

Figure 1a:
BIRMINGHAM HIP RESURFACING (BHR) device with one-piece cup

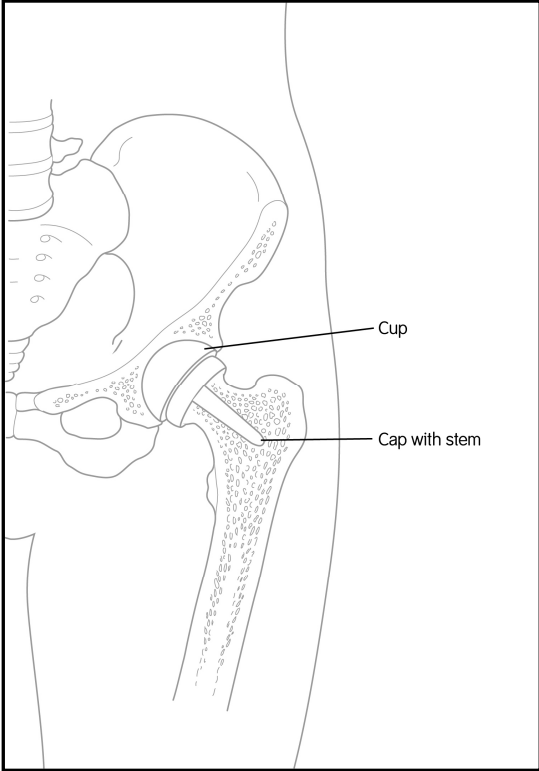


Figure 1b:
BIRMINGHAM HIP RESURFACING (BHR) device with two-piece cup

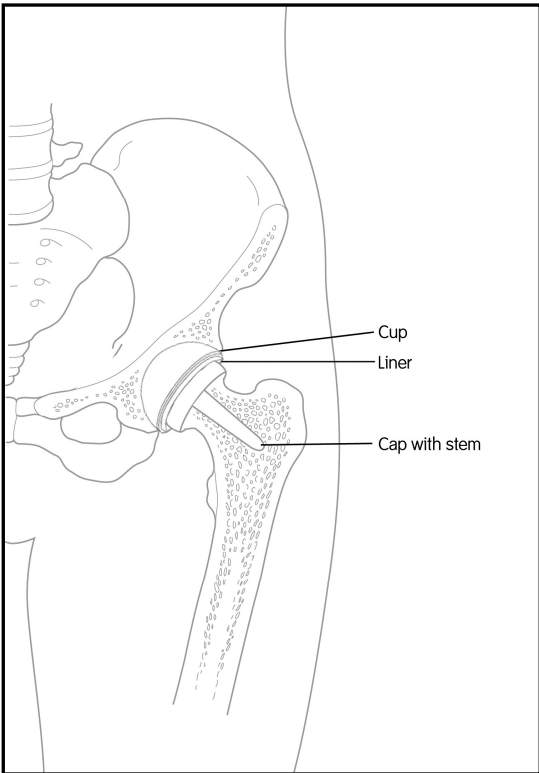
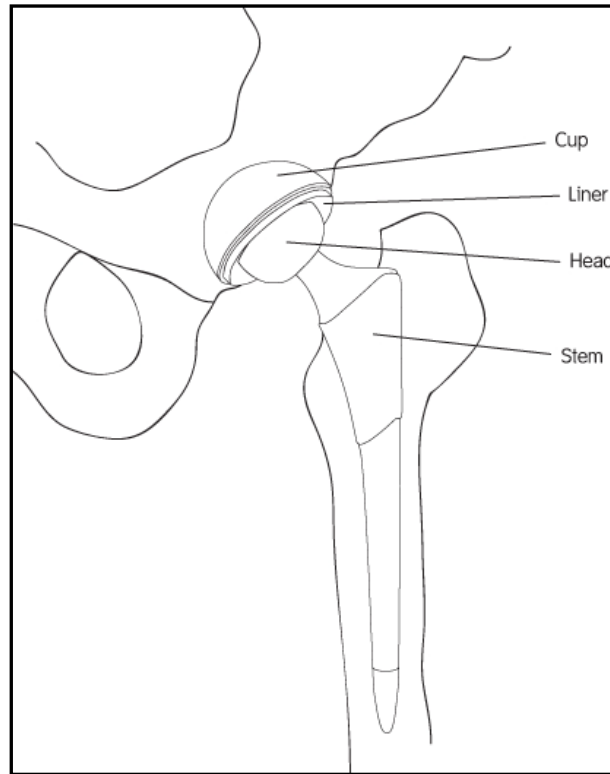


Figure 2:
Total Hip Replacement (THR) device



2.0 What Is the Purpose of the BHR Device?

The BHR System relieves hip pain and improves hip function by replacing the parts of your hip that have been severely damaged by degenerative joint diseases. The names of such diseases include osteoarthritis, rheumatoid arthritis, traumatic arthritis, dysplasia, or avascular necrosis.

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 replacement due to an increased possibility of requiring future hip joint revision.

3.0 When Should the BHR Device Not Be Used? (Contraindications)

You should not receive the BHR device if:

- You have an infection of the body or blood.
- Your bones are not yet fully grown.
- You have any blood vessel-related disease, muscle-related disease, or nerve-and-muscle-related disease that will prevent the artificial hip joint device from remaining stable or that may prevent you from following instructions during the recovery period.
- Your bones are not strong enough or healthy enough because:
 - You have severe bone loss (osteoporosis) or have a family history of severe bone loss,
 - You have bone loss (such as avascular necrosis) affecting more than half of your femoral head,
 - You have multiple fluid-filled cavities (cysts) greater than 1 centimeter of your femoral head,
 - A test (such as DEXA scan) may be needed to determine your level of bone loss.

- You are a female of child-bearing age. It is unknown whether metal ions released by the device could harm an unborn child.
- Your kidneys are not working very well (function is significantly impaired). You will need testing (creatinine, GFR, BUN) before and/or after surgery to test your kidneys.
- You have a suppressed immune system due to diseases such as AIDS or are receiving high doses of corticosteroids.
- You are severely overweight.
- If you have had reactions to wearing metal jewelry, you may have what is called “metal sensitivity.”

Your doctor will need complete information about your overall health to determine whether the BHR device is right for you. So, tell your doctor about **any** health problems you have, even if it is not related to your hip, because some medicines as well as diseases (such as diabetes) can affect your kidney or bone strength in the future.

4.0 What Are Some of the Potential Benefits of the BHR Device?

Your surgeon has decided that you will benefit from hip replacement surgery. When thinking about the benefits of the BHR device, you should compare the possible risks and benefits of the device to the risks and benefits of other types of artificial hip replacement devices:

- Hip resurfacing versus a total hip replacement:

With a hip resurfacing device, the surgeon covers your hip socket with a metal cup, and covers your femoral head with a metal cap (See Figures 1a and 1b). The BHR System is a hip resurfacing device. With a total hip replacement device, the surgeon covers your hip socket with a cup and replaces your femoral head with a metal ball attached to a long metal stem. The metal stem is inserted into your thighbone. (See Figure 2).

- Metal-on-metal versus metal-on-plastic or ceramic-on-ceramic:

With metal-on-metal systems, the cap (ball) and the socket components are made from highly-polished metal. The BHR System is a metal-on-metal system. Other hip systems can have a metal ball with a plastic-lined socket (metal-on-plastic), or a ceramic ball with a ceramic-lined socket (ceramic-on-ceramic).

Each of the device types discussed above can significantly improve hip pain and function. However, specific potential benefits of the BHR System include:

- The BHR’s metal cup will not chip or crack as ceramic components can.
- The BHR does not cause thighbone (femoral shaft) fractures as total hip replacement systems can.
- The BHR may make future revision surgery easier because hip resurfacing surgery leaves your femoral head in place and there is no large metal stem placed in the thighbone. Revision surgery of a total hip replacement where your femoral head has already been removed and a large stem is already in place can be a more difficult operation.
- Dislocation of the ball head from the socket is less common with the BHR device than with total hip replacement devices. In the clinical study, 9 of 2,385 (0.3%) BHR hips experienced dislocation, compared with between 3 of 333 hips (1%) and 7 of 165 hips (4.2%) of total hip replacement patients from comparison studies. (See section 6.0.)
- One-piece acetabular component versus two-piece acetabular component designs:

- The BHR acetabular component is provided in a one- and two-piece design.
- The potential benefits of the two-piece design for the patient include an option for additional fixation using bone screws, and an easier revision to a total hip replacement system if such replacement becomes necessary in the future. With the two-piece design, if the metal outer shell is well fixed, the surgeon has the option at a future revision surgery of leaving the metal outer shell in place without further disturbing the hip socket bone and replacing the metal liner with a plastic liner that can mate with a new total hip replacement system head and femoral stem.
- The potential benefit of a one-piece design is that there is no risk of unintentional component disassembly.

5.0 What Are Some of the Potential Risks of the BHR Device?

The potential risks of any hip joint replacement include:

- Damage to blood vessels, or temporary or permanent nerve damage during surgery,
- Sudden drop in blood pressure during surgery due to the use of bone cement
- Blood circulation problems because of surgery or during recovery including blood clots in the legs or lungs or heart attack.
- Allergic reactions to the device material or to medications you are given,
- Surgical wounds that take a long time to heal due to many reasons such as poor skin condition, infection, poor blood circulation, bad hygiene, etc.
- Infection related to surgery and wound healing. 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,
- Dislocation of the hip, device loosening/shifting, or device wear/breakage due to muscle and fibrous tissue lack of firmness (laxity). Device placement in the wrong position in the bone, poor attachment of the device to the bone, too much weight or activity put on the device, or accidents affecting the hip joint like falls (trauma),
- Damage to the bones and tissue (tissue necrosis) near the hip joint, including loss of the surrounding bone (osteolysis) or staining of the hip joint fluid (metallosis) due to wearing away of the metal parts over time.
- Change in the length of the leg in which the device is placed,
- Device breakage due to weakening of the metal over time (fatigue fracture),
- Bone breakage due to osteoporosis or accidents (trauma),
- Bone loss or too much bone formation near the implants in response to the surgery or to the presence of the device in the bone.
- Increased hip pain and/or reduced function.
- 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).

These potential adverse effects may require medical attention or additional surgery. Rarely do complications lead to death.

The potential risks of the BHR device as compared with a total hip replacement system include:

- The risk of femoral neck scratching (notching) during surgery that can lead to femoral neck fracture after surgery. This occurred in 10 of 2,385 (less than 1%) BHR hips in the clinical study.
- The risk of femoral head collapse. This occurred in 15 of 2,385 (less than 1%) BHR hips in the clinical study.
- The risk of avascular necrosis. This occurred in 35 of 2,385 (1%) BHR hips in the clinical study.
- If the ball cap part of the BHR device must be removed (revised), your surgeon will likely put a total hip replacement metal stem in your thighbone (see Figure 2). There is currently not a metal femoral head and stem for use with a BHR resurfacing cup (one- or two-piece acetabular component design). Therefore, if you have a one-piece BHR acetabular component, your surgeon will have to remove the socket part of the BHR device even if it is not a part of the problem. However, if you have a two-piece BHR acetabular component, then your surgeon can replace the metal liner of the acetabular cup with a new plastic liner that will mate with the new total hip replacement system head and femoral stem. The surgeon can leave your existing metal shell in place, if it is well fixed, without further disturbing your socket bone.
- If the two-piece BHR acetabular component is used, there is a risk of the potential disassembly of the two components.
- Patients who have a greater risk of revision than other patients include those who are female; who require a smaller component size ($\leq 44\text{mm}$); have a mal-positioned device; are obese; or, who have a diagnosis of avascular necrosis. The more risk factors a patient has, the greater the risk of procedure failure requiring a revision to the hip.

The complications described above may require surgery to change from the BHR device to a total hip replacement device. You should compare these risks to the potential benefits of a BHR system, as described above. See also *“What Problems May Occur After Your Operation?”*, Section 9.0.

6.0 What Do the Clinical Studies Show?

A clinical study was performed using a BHR femoral head resurfacing component and a one-piece acetabular cup design to evaluate the safety and effectiveness of the BHR device. The use of the BHR femoral head resurfacing component with the two-piece acetabular cup design has not been studied clinically. Complication (safety) information was collected from the entire group of 2,385 study hips. Effectiveness information was collected from the first 1,626 of the 2,385 hips because these 1,626 hips have the longest follow-up. There is 5 year follow-up information for 546 of these 1,626 hips.

Safety Data

The overall complication rate and the types of complications in the BHR study group were generally similar to the complications reported for other hip replacement systems. The few differences between different types of complications are discussed under Section 5 - *“What Are Some Potential Risks of the BHR Device?”* and Section 4 - *“What Are Some Potential Benefits of the BHR Device?”*

Complications led to revision surgery in 27 out of 2,385 hips. See Table 1 for a summary of reasons for the revision. The 1.13% (27/2,385) revision rate at 5-years after surgery from all complications was comparable to the revision rates reported for total hip replacement devices.

There were no deaths related directly to use of the device in the study. All deaths were from other medical problems.

Table 1: Reasons for Revision Surgeries in BHR Study (N=2,385 Hips)		
Reason for Revision	Number of Revisions	Average time to revision in years
Femoral neck fracture	10	0.198
Infection	8	3.119
Collapsed femoral head	6	2.172
Avascular necrosis	2	0.661
Dislocation	1	0.003
TOTAL	27	

Effectiveness Data

Effectiveness was determined by looking at:

- Survivorship: The cumulative percentage of patients that did not need revision of the BHR by 5 years after surgery.
- Oswestry Hip (OSHIP) Score: The OSHIP score asks patients questions about their hip pain, hip function, and hip movement. Based on the patient response to the questions a total score is calculated. The total score ranges from 0 (worst) to 100 (best). A score of 80 or better is generally considered a good clinical result.
- Patient Satisfaction: Patients in the study were asked to rate their satisfaction with the result of the BHR surgery on a scale of 0 (worst) to 4 (best).

The results are shown in Table 2.

Table 2: Effectiveness Measures at 5 years After Surgery	
Effectiveness Measure *	5 years After Surgery
Survivorship: cases with device in place (not revised)	2,358 of 2,385 (98.5%)
OSHIP score: of patients with a good result (80 or better)	509 of 546 (93.2%)
Patient Satisfaction: patients who responded “Pleased” or “Extremely Pleased” with their results	543 of 546 (99.5%)

* Survivorship data was for the safety cohort of 2,385 hips. OSHIP and Patient Satisfaction data were for a subgroup of 1,626 hips. In a unilateral hip analysis, 334 of 360 patients (92.7%) had a good OSHIP score result (80 or better), and 357 of 360 patients (99.2%) were “Pleased” or “Extremely Pleased” with their result.

7.0 What Can You Do Before Your Surgery?

Your doctor may want you to meet with a Physical Therapist (PT) even before the surgery. The PT may give you some tips on preparing your house for rehabilitation, and on how you should sleep, get out of bed, sit, get up, and walk following surgery. Some things you can do before surgery to prepare for the rehabilitation period are:

- Add extra cushions to couches and chairs. The extra height will make it easier for you to lower and raise yourself from the chair.
- Have armchairs available. During rehabilitation, you may be told only to sit in armchairs, as you will need the arms to help you sit down and get up.
- Arrange to have an elevated toilet seat and/or support bars fitted in your bathroom.
- Move items you may need to reach to shelves or tables above waist level.
- Remove all throw rugs and anything else on the floor that might cause you to slip or trip and fall.

8.0 What Can You Expect After Your BHR Hip Resurfacing Operation?

Most patients are in the hospital from 4 to 6 days. The surgery usually takes 2 to 4 hours to perform. You will use walking support (canes, crutches) for about six weeks after surgery while your hip muscles are healing. You may be told not to bend your hip or waist to more than a 90-degree angle during the healing time (rehabilitation).

Before you go home, your Physical Therapist (PT) will teach you to climb stairs and how to move from a bed, chair, and car. Your PT may also give you a list of exercises to do at home every day. These exercises will help you become as independent as possible in your personal care and daily activities after you return home. Physical therapy will also help prepare you for more difficult exercises, movement, and activity.

Most of your therapy and healing (rehabilitation) will occur once you have checked out of the hospital. Your PT will design an exercise program to increase motion and strength of your hip, and will teach you the exercises, making sure you know proper way to do the exercises before you begin. The success of your rehabilitation is very dependent on how dedicated you are to the physical therapy program.

9.0 What Problems May Occur After Your Operation?

Early Infection

Contact your doctor if you experience any of the following signs of infection:

- Drainage and/or foul smell from surgical cut (incision).
- Fever/temperature above 100.4°F (or 38°C) for two days.
- Redness or swelling or increased pain at or near the surgical cut.

Late Infection

To protect your hip joint from infection after your surgery, you will need antibiotics before the following procedures:

- Internal examinations of the bladder (cystoscopy), colon (colonoscopy) or rectum (proctoscopy).
- Dental work including teeth cleaning.
- Surgery of any kind.
- Placement of a tube into the ureter to drain urine from the body (urinary catheterization).

Infections can travel from other parts of your body to your new hip. If you have any infection in any part of your body, contact your doctor.

Late Pain or Instability

Some pain is normal and expected during your rehabilitation period, and the pain should slowly decrease in the weeks following surgery. If you experience any serious, immediate, constant hip pain or pressure or feeling of unsteadiness, or if you are suddenly unable to put weight on your hip after the early post-operative pain has gone away, you should contact your doctor. These

signs (symptoms) may be a signal of a serious problem (such as bone breakage, dislocation, infection, device loosening, movement, or breakage). Any of these problems may require medical attention including additional surgery.

Continuing Evaluation

Follow your doctor's schedule for routine examinations after surgery. Routine examinations will include regular X-ray exams to look for any problems such as hip bone or device breakage, position changes, or anything abnormal. X-rays will also check the progress of bone healing around the implant.

10.0 What Are Some Warnings to Keep in Mind After Surgery?

Take care to protect your joint replacement from too much stress and follow your surgeon's instructions regarding activity level and rehabilitation.

- Do not perform high impact activities such as running and jumping during the first post-operative year while the bone is healing.
- Early device failure (breakage or loosening) may occur if you do not follow your surgeon's limitations on activity level. Early failure can happen if you do not guard your hip joint from overloading due to activity level, failure to control body weight, or accidents such as falls.
- Loosening of the hip joint device may cause too much wear of the metal parts and result in very small metal particles being created. This can result in bone loss around the implant causing more loosening.
- Early device failure or bone loss may require additional surgery to remove the device (revision surgery).
- Artificial hip joints can wear out over time and may require replacement.
- If a physician prescribes an MRI scan for you, inform the physician that 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.

11.0 Are there Instructions When You Leave Home or Travel?

Your new hip device may activate metal detector alarms. Tell the security attendant about your artificial hip when passing through security checkpoints in airports, stores, and public buildings.

12.0 Where Else Can You Get User Assistance Information?

Please discuss any questions regarding your hip surgery with your surgeon. For further information regarding the BHR System components, you may also contact the device manufacturer:

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