



REFLECTION[®] Ceramic Acetabular System

PATIENT INFORMATION

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Glossary of Terms

- Artificial: Man-made.
- Brittle: Easily broken.
- Ceramic: In this device, a very hard material made from aluminum and oxygen (Al_2O_3).
- Hip Dislocation: Separation of the ball and cup in an artificial hip replacement device.
- Migration: movement of the device out of its original position .

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- **Non-inflammatory Arthritis Disease:** A condition that causes the loss of cartilage and bone in a joint that eventually leads to increased joint pain and reduced joint function.
- **Periarticular calcification:** build-up of bone in the soft tissues and bony structures near and around the joint.
- **Prosthesis / Prosthetic:** An artificial replacement for a part of the body.
- **Range of Motion:** all the movements of the leg in multiple directions due to the movement of the ball and socket joint.
- **Rehabilitation:** Movement exercises, periods of rest, and other treatments that assist the body's healing process.
- **Revision:** Replacement of a failed implant with a new implant.
- **Total Hip Replacement:** surgical replacement of the hip ball and socket joint.

1. Introduction

This document provides information to help you make an informed decision about your hip surgery and the hip prosthesis called the REFLECTION[®] Ceramic Acetabular System.

2. Which Patients Might Benefit from the REFLECTION Ceramic Acetabular System?

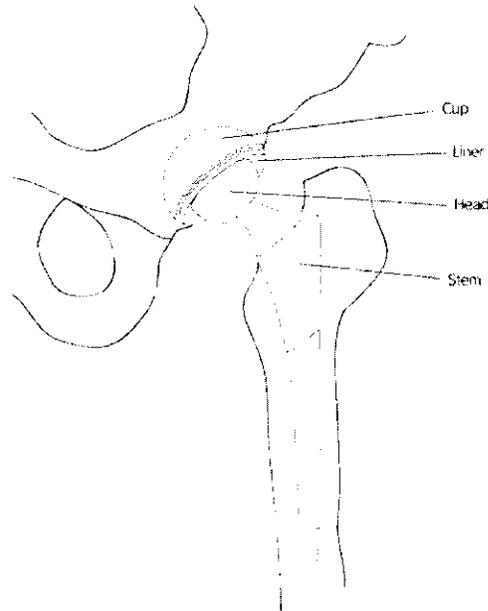
Your hip is a socket and ball joint where the thigh bone and pelvis come together. As your leg moves, the ball of your thigh bone (called the femoral head) moves and rotates against the socket portion of your pelvic bone (called the acetabulum). If your hip joint is diseased due to certain kinds of arthritis,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

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3. What is the REFLECTION Ceramic Acetabular System?

The REFLECTION Ceramic Acetabular System (see diagram, figure 1) is an artificial total hip replacement medical device. An artificial hip replaces the normal socket and ball hip joint with a prosthetic device. Total hip replacements are typically made of a metal ball (head) attached to a metal shaft (stem) that is placed in the thigh bone (femur); and a socket (liner) made of plastic (called polyethylene) is placed in a metal cup that is attached to a part of the pelvis (acetabulum). However, in the case of the REFLECTION Ceramic Acetabular System an alumina ceramic material is used for both the ball and socket instead of the metal ball and plastic socket. Therefore, the ceramic ball moves and rotates against the ceramic socket. The REFLECTION Ceramic Acetabular System is approved for use in patient's who have a hip joint that is damaged by non-inflammatory arthritis disease.

Figure 1



4. When Should the REFLECTION Ceramic Acetabular System Not Be Used?

The REFLECTION Ceramic Acetabular System should not be used in patients with any of the conditions listed below. Your doctor will help you understand if any of these conditions apply to you.

- poor bone quality
- when bones have not yet matured and you are still growing
- nerve or muscle condition that would place extreme load on hip or could cause recurrent dislocation of the hip
- active joint infections or chronic systemic infection such as hepatitis or HIV infection
- obese patients where obesity is defined as three times normal body weight

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5. What Are Some Possible Complications?

Complications associated with Ceramic on Ceramic Hip system replacement surgery include, but are not limited to, the following:

- unintended bone breakage during implant of the prosthesis
- difficulty implanting ceramic components including possible breakage of ceramic components during or after surgery
- hip (implant) dislocation
- ceramic wear debris
- additional (revision) surgery to remove some or all components of the prosthesis

In addition to the complications listed above, any type of hip replacement surgery has risk of complications. This includes, but is not limited to, the following:

- wear debris of implant components (debris can travel to other parts of the body where it can potentially cause an unwanted reaction requiring further medical treatment)
- fracture, migration (movement), loosening, or dislocation of the hip implant requiring revision surgery to remove some or all components
- pain
- unintended bone fractures during implant of the prosthesis
- allergic reaction to implant material
- excessive bleeding

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- nerve damage
- leg length change
- blood clots
- bruising (hematoma)
- wound closure problems
- infection
- periarticular calcification
- heart attack
- GI and Urinary complications
- decreased Range of Motion
- aggravation of other joint or back conditions
- reactions to anesthesia
- pneumonia
- death

Please talk to your doctor about the complication rates related to treatment with the REFLECTION Ceramic Acetabular System.

6. What Are Some Benefits of the REFLECTION Ceramic Acetabular System?

The REFLECTION Ceramic Acetabular System has the same benefits as other hip replacement devices – relieving pain and restoring mobility to return you to

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your activities of daily living. In a clinical study, the REFLECTION Ceramic Acetabular System, which uses an alumina ceramic ball rotating against an alumina socket, was shown to be as successful as the same Reflection Hip system which used an alumina ceramic ball rotating against a plastic socket (control). Success was defined as:

- no revision of any component,
- a Harris Hip Score of 80 points or more, and
- no unacceptable x-ray findings.

The Harris Hip Score is a commonly used evaluation method to measure the clinical progress of total hip replacement patients. Please talk with your doctor for a more complete discussion of the results from the research study.

Although this clinical study also included patients diagnosed with inflammatory arthritis or patients requiring a revision of a previously unsuccessful hip implant, there was not enough information collected for these two groups to determine if the REFLECTION Ceramic Acetabular System is a good hip replacement choice for patients with these conditions.

7. What Are Some Questions That I Should Ask My Surgeon?

Follow all doctor's or other treating physician's instructions. When patients are scheduled for surgery, they often receive instructions and information to explain the comprehensive preoperative requirements of total hip replacement. Ask your doctor to provide such written instructions about what to do and what not to do prior to and following total hip replacement. Some important questions are:

- What exercises should I do before surgery?
- What is the expected average length of hospital stay?

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- Would you describe some of the equipment (eg, oxygen, urinary catheter, antiembolism stockings, sequential compression boots) used while in the hospital?
 - You may receive extra oxygen given through a nose piece (nasal cannula) while in surgery and for a short time after surgery. A small tube (catheter) may be inserted in your urinary tract to drain urine during and for a short time after surgery. You may have special stockings or boots placed on your legs to reduce the chance of blood clots.

- What medications might I have to take?
 - You may take blood thinners and/or antibiotics before and after surgery. You will receive pain medication after surgery. Other medications may be prescribed to you based on your medical condition.

- What are some precautions and possible complications that I should know about?
 - It will be important for you to follow instructions given by your surgeon and physical therapist and to participate in any necessary long-term follow-up.
 - Hip replacement is major surgery. There are many possible complications. One possible complication that you may directly influence is called a “dislocation”. A dislocation is when the ball joint comes out of the socket. A dislocation can result from certain activity that is not recommended after surgery such as crossing legs, low bending over at the waist, sitting in low chairs or toilets, sharp twisting at the waist.

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- What equipment and/or medications will I need at home after surgery?

Additionally, many hospitals now offer preoperative joint replacement patient education classes that include detailed information about the above-mentioned items, as well as other topics. You should attend these classes if the classes are offered at your hospital.

8. What Happens During the REFLECTION Ceramic Acetabular System Surgery?

Implanting the REFLECTION Ceramic Acetabular System is like any other total hip replacement surgery. After you are given drugs to make you sleep (anesthesia), your doctor (surgeon) will make a cut (incision) in the area of your diseased hip. The ball and socket joint will be prepared so that it can accept the artificial replacement ball and socket implant device. Your doctor will implant the ball and socket joint that has been sized to fit your body proportions in the space provided, will secure it, and will close the incision.

9. What Should I Expect After Surgery?

After surgery, your doctor and/or hospital personnel will instruct you about any limitations for moving your legs and body while in or out of bed. You will likely begin physical therapy soon after surgery, and therapy will continue some weeks after surgery. You may expect the following:

- You will have a large bandage on your hip and a small drainage tube to help drain excess fluids from the joint area.
- You will experience mild to severe pain after surgery, but your surgeon will provide medicine to control your pain.
- The hospital will provide you with special stockings and/or medication to reduce the risk of blood clots.
- Most hip replacement patients will be in the hospital three to five days.

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- Your length of hospital stay will depend on your medical condition and your progress in rehabilitation.
- In the days and weeks following surgery,
 - Your doctor will decide how much weight you will be able to bear on the operated hip (this will determine how active you can be during rehabilitation).
 - You will use canes, crutches, walker, or other assistance devices to reduce the weight on your hip.
 - Carefully follow your doctor's instructions regarding how much weight to place on your hip during rehabilitation.
- Until your doctor says you can walk on your own, you must have someone to help you walk to the toilet or perform other activities of daily living that may cause too much motion of the hip. Carefully follow your doctor's instructions about how much, and in what direction, you move (or do not move) your hip and leg.
- You will need to visit your doctor at various times after your surgery to check your hip pain and its function.
- You will need to go for X-rays on a regular basis to detect any problems such as hip bone or implant breakage, position changes, or anything abnormal. X-rays will also check the progress of bone healing around the implant.
- Because of the brittle nature of the ceramic implant parts, your ceramic ball or cup implant could break, or become damaged, in extreme cases of strenuous activity (such as during sports activities) or trauma (such as a hard blow during a car accident). At any time, if you notice any sudden change in sensation or feeling in your hip such as "grinding", contact your doctor immediately.
- It is important to follow your doctor's instructions carefully to recover from

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surgery as quickly as possible.

NOTE: Please call your doctor if you experience any of the following symptoms:

- Signs of infection (i.e. fever, chills, redness around incision, increased pain, the feeling of pressure in the hip, or difficulty walking)
- Bleeding or excessive drainage from your incision(s)
- Sudden onset of severe pain or significant increase in your pain level
- Loss of sensation (feeling), or significantly decreased sensation in your leg/foot
- Increased or persistent shortness of breath
- Audible clicking noise or grinding noise in your hip joint with movement

10. Are There Alternative Treatments?

Although your doctor is planning to use the REFLECTION Ceramic Acetabular System for your hip replacement, you should be aware that there are alternative treatments. Patients, in consultation with their doctor, are likely to choose from one or more of the following options.

- No treatment. With this option, your doctor will continue to observe your hip but will advise you to delay having hip surgery.
- Your doctor may recommend exercise, medicine, a hip brace or a combination of any of these treatments.
- Hip fusion surgery that consists of surgically attaching the femur (thigh bone) to the pelvis (hip) causing the two bones to heal together to become one.

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- Total Hip replacement with another commercially available implant or implant parts made of different materials. Choices available to you include a metal femoral head and a plastic liner, a metal femoral head and a metal liner, or a ceramic femoral head and plastic liner, or another hip replacement system consisting of a ceramic ball and ceramic liner.

11. Who Do I Talk To If I Still Have Questions?

This document is provided to give you information about your treatment options. It is not intended to replace professional medical care or provide medical advice. If you have any further questions or need additional information about the REFLECTION Ceramic Acetabular System, please speak with your doctor.

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