

# R3 delta Ceramic Acetabular System

## PATIENT INFORMATION

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## ***Glossary***

**Acetabular:** The socket part of the hip joint.

**Artificial:** Man-made.

**Avascular Necrosis:** A condition that results in death of the bone in the femoral head and/or neck (the ball part of the hip and bone below the ball) because of too little or no blood flowing to it.

**Body Mass Index (BMI)** – A number calculated from a person's weight and height to estimate their body fat. The BMI is calculated by dividing the person's weight in kilograms by the square of height in meters (square of the height = height multiplied by height).

**Brittle:** Easily broken.

**Cartilage:** A smooth connective tissue that covers the ends of bone within a joint.

**Ceramic:** In this hip implant, a very hard material made from alumina ( $\text{Al}_2\text{O}_3$ ) and zirconia ( $\text{ZrO}_2$ ).

**Elevated Metal Ions:** Increased metal particles with an electric charge (ions) from the hip implant. These may cause problems around the joint and may enter the blood. In some cases the levels of certain metal ions in the blood may be higher than what is usually found in the blood (elevated).

**Femur:** Thigh bone.

**Dislocation of artificial hip replacement:** Separation of the ball and cup.

**Implant:** A man-made product that takes the place of a part of the body and is put in or implanted during surgery (operation). A hip implant is a product that replaces part of the hip joint.

**Migration:** Movement of the implant from its original position.

**Non-inflammatory Degenerative Joint Disease (NIDJD):** A general term used to describe a hip joint damaged from osteoarthritis, avascular necrosis, and/or post-traumatic arthritis.

**Osteoarthritis:** A loss of bone and/or cartilage in the hip joint that may lead to pain and stiffness.

**Periarticular calcification:** Build-up of bone in the soft tissues (muscles, tendons, and/or ligaments) around the joint.

**Post-Traumatic Arthritis:** A condition that results in loss of bone and/or cartilage in the hip joint after a hip injury.

**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, rest, and other treatments that help the body heal.

**Revision:** Replacement of an existing implant with a new implant.

**Skeletally mature:** The bones of the skeleton have finished growing.

**Titanium:** A very strong and light metal.

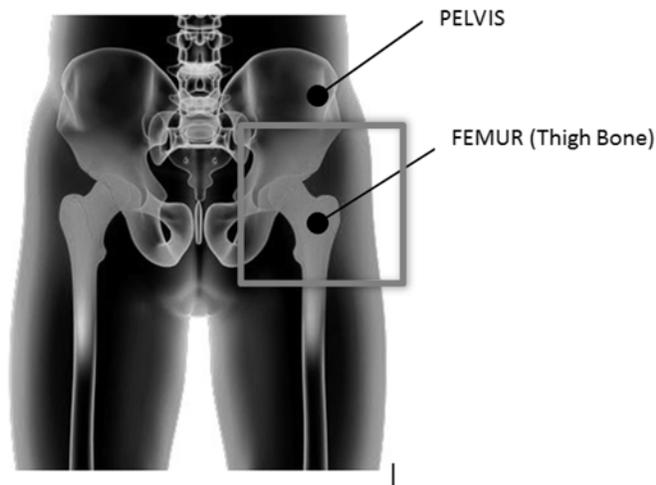
**Total Hip Replacement:** When an artificial or man-made ball and socket replaces the patient's own hip joint.

**Zirconia toughened alumina:** A hard ceramic material made of alumina and zirconia.

## ***Introduction***

The purpose of this document is to provide you with information about the R3 delta Ceramic Acetabular System and to help you understand the risks and benefits that are associated with a total hip replacement surgery. This brochure will help to explain what your hip joint looks like, and what would happen to you before surgery, during surgery and after surgery. All of this information is provided to help you make an informed decision about a potential total hip replacement surgery using the R3 delta Ceramic Acetabular System.

Your hip is a ball and socket joint where the thigh bone and pelvis join together (Figure 1).



**Figure 1.**

As your leg moves, the ball part (called the femoral head) of your thigh bone (also called the femur bone) moves and rotates against the socket part of your pelvic bone (called the acetabulum), see Figure 2. If your hip joint is damaged due to certain kinds of arthritis, the cartilage and bone of the hip joint become worn out. It may get harder to move your hip and your hip may become more painful over time. Your surgeon has advised you that your hip joint is damaged and that hip replacement surgery is a treatment option.

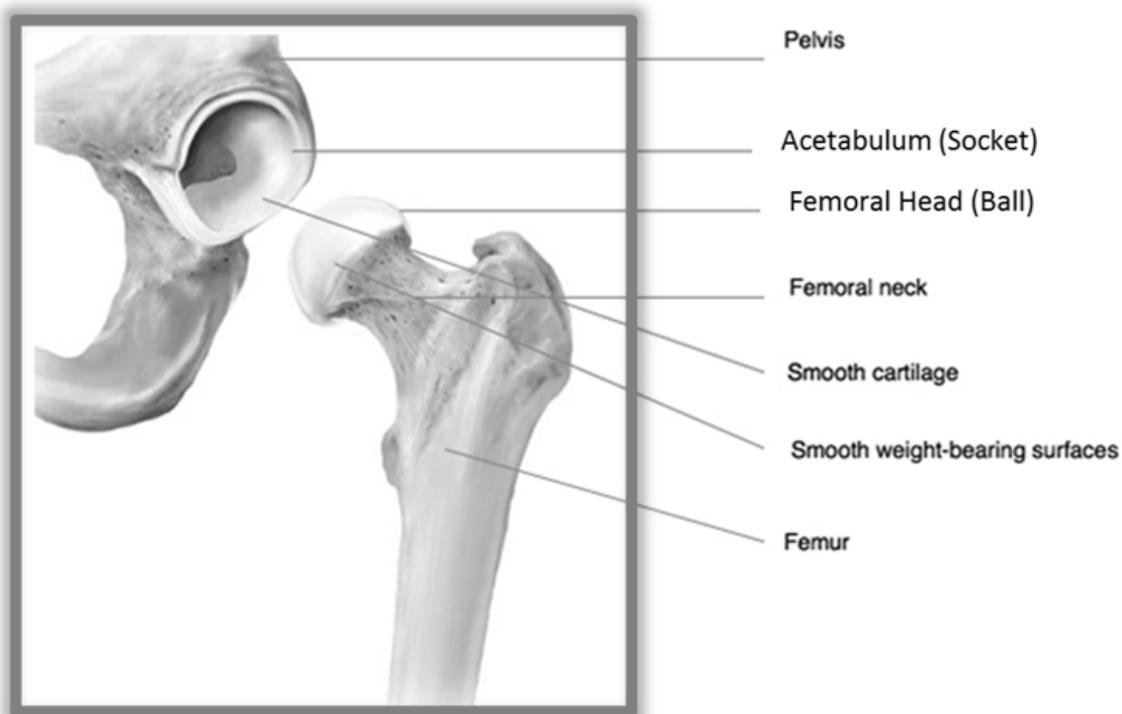
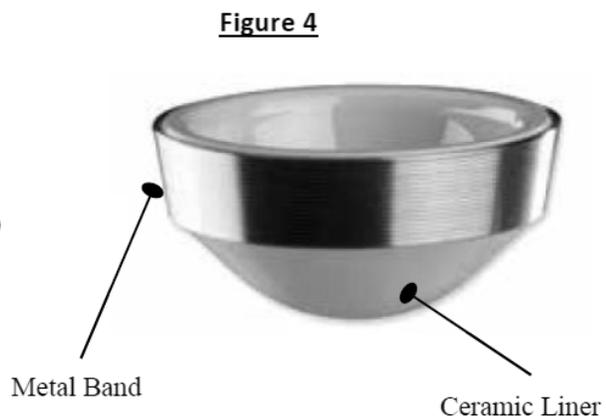
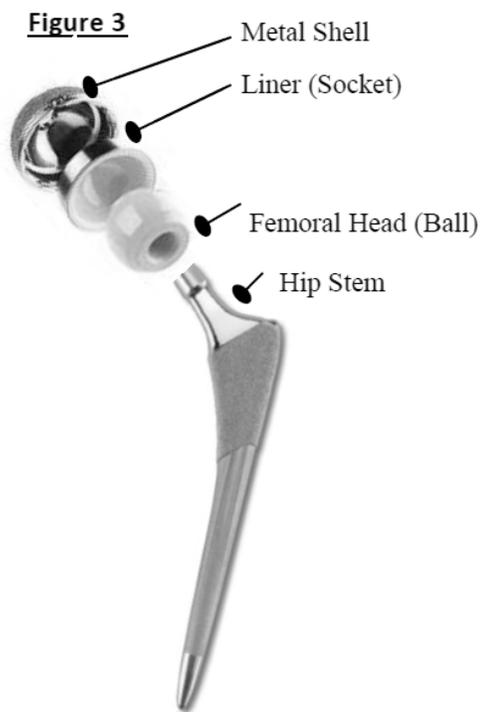


Figure 2.

### ***What is the R3 delta Ceramic Acetabular System?***

The R3 delta Ceramic Acetabular System (see diagram, Figure 3) is used for total hip replacements. An artificial hip replaces the patient's socket and ball in the hip joint. Total hip replacements are typically made of a metal ball (head) connected to a metal shaft (stem) that is placed in the thigh bone (femur), and a socket (liner) made of plastic (called polyethylene) placed in a metal cup that is connected to a part of the pelvis (acetabulum). However, in the case of the R3 delta Ceramic Acetabular System a ceramic material is used for both the ball and socket instead of the metal ball and plastic socket. The ceramic material is zirconia-toughened alumina. The R3 delta Ceramic Acetabular system includes a shallow metal shell (acetabular shell), a ceramic socket (liner), a ceramic ball, and a metal stem. The ceramic ball moves and rotates against the ceramic socket. The R3 delta Ceramic Liner has an outer metal (titanium) band (Figure 4) that strengthens the ceramic liner and allows it to lock into the metal shell.



***For what conditions do surgeons use the R3 delta Ceramic Acetabular System?  
(Indications)***

The R3 delta Ceramic Acetabular System can be used in skeletally mature patients who have a hip joint that is damaged by non-inflammatory degenerative joint disease (NIDJD). NIDJD is a general term used to describe a hip joint damaged from osteoarthritis, avascular necrosis and/or post-traumatic arthritis.

- Osteoarthritis: A loss of bone and/or cartilage in the hip joint that may lead to pain and stiffness.
- Avascular Necrosis: A condition that results in death of the bone in the femoral head (the ball part of the hip) and/or in very rare cases the neck (the bone below the hip ball) because of too little or no blood flowing to it.
- Post-Traumatic Arthritis: A condition that results in loss of bone and/or cartilage in the hip joint after a hip injury.

## ***What type of patient should not have the R3 delta Ceramic Acetabular System? (Contraindications)***

The R3 delta Ceramic Acetabular System should not be used in patients with any of the conditions listed below. Your surgeon will help you understand if any of these conditions apply to you.

- Poor bone quality: the bone that would support the artificial hip is not strong enough.
- When you are still growing.
- Nerve or muscle condition that would place extreme weight on hip or could cause repeated dislocation of the hip.
- Current joint infections or a chronic systemic infection (a persistent infection in some part of your body) such as hepatitis or HIV infection.
- Severely obese patients where severe obesity means a Body Mass Index (BMI) that is 40 or higher. Body Mass Index (BMI) is a person's weight in kilograms divided by the square of their height in meters. For example, if a person is 5 feet 9 inches tall (1.75 meters) and they weigh 271 pounds (122.9 kilograms), or more, their BMI is 40 or higher (122.9 kilograms/(1.75 meters x 1.75 meters)).
- Patients with a known allergy to any of the implant materials

## ***What are the things you must do to avoid potentially serious harm if implanted with the R3 delta Ceramic Acetabular System? (Warnings/Precautions)***

- **WARNING** - Do not place a large amount of stress (such as that from heavy exercising or work) on your artificial hip. An artificial hip joint can fail (not work like it was supposed to) if a lot of stress is placed on it. In addition, the R3 delta Acetabular System is made of ceramic that is brittle and can break if you put a lot of stress on your hip.
- **WARNING** - Call your surgeon immediately if you notice any sudden change in feeling in your hip or hear any noises such as clicking, squeaking, or grinding. This noise might mean that the implant position has changed or the implant has broken. If the implant fails, you will need to have a second surgery to have it taken out.

- **WARNING** - Inform any physician who wants you to have a MRI (Magnetic Resonance Image) that the R3 delta Ceramic Acetabular System has not been tested to see if it is safe to use with a MRI machine. The R3 delta Ceramic Acetabular System has not been tested in patients having a MRI, so it is not known if the implant will heat up or move within the bone if you have a MRI.
- **WARNING** -Follow all instructions from your surgeon regarding activities and work that are not recommended after surgery. Some movements, such as crossing your legs, low bending over at the waist, sitting in low chairs or on low toilet seats, or sharp twisting at the waist, may cause something called “dislocation”. This is when the ball part of the hip joint comes out of the socket part. If this happens, you may feel pain and your hip joint will not move properly. The ball part of the hip joint will need to be put back in the socket either by the surgeon moving it back into place while you are sedated (given medicine to not be aware of the surgeon putting your hip back in place) or with another surgery. Once your hip is back in place, your surgeon may fit you with a brace to keep the hip in the correct position. Your surgeon will give you instructions based on you and your hip implant.
- **WARNING** - Call your surgeon if you experience any of the following signs or symptoms:
  - Signs of infection, such as fever, chills, redness around your incision, increased pain, the feeling of pressure in the hip, or difficulty walking. Infection can cause an implant to fail, which would require a second surgery to take out the hip implants.
  - Bleeding or continued oozing of liquid (excessive drainage) from your incision(s) that is more than what your surgeon told you to expect. Bleeding or drainage may be a sign that your wound is not healing properly and you need to have the surgeon examine it. You may need to take medicine, or you may need to have the incision re-opened to make sure it will heal correctly.
  - Severe pain that comes on quickly or an increase in your pain level that limits being able to perform activities. This kind of pain may indicate that there is a problem with your hip replacement and you should call your surgeon to see if he/she feels you should be examined.
  - Loss of feeling or the feeling is dull or numb in your leg/foot. This may mean that there is a problem with your hip replacement and you should call your surgeon to see if he/she feels you should be examined.

- **CAUTION** - Follow your surgeon's instructions to get better after surgery and to know how much weight to place on your hip after surgery and during rehabilitation. Over time, the amount of weight you can place on your hip will be increased. Your surgeon will tell you how much weight you can place on your hip during each of your follow up visits. If you put too much weight on your hip you may feel pain, you may fall causing other injuries such as a broken bone, or you could have a hip dislocation.
- **CAUTION** - Have someone at home help you walk to the toilet or perform other activities of daily living until your surgeon says you can walk on your own. Examples of activities that may be hard to do on your own after surgery include, but are not limited to, putting on and taking off pants, putting on and taking off shoes and socks, and bending over to pick up things from the floor. If you live alone and do not have anyone who can help you, speak with your surgeon to let him/her know this. Before you are discharged from the hospital, the discharge planning staff will talk with you about how you will manage after your hip surgery.
- **CAUTION** - Follow your surgeon's or physical therapist's instructions about how much, and in what direction, you may move (or may not move) your hip and leg after surgery. If you do not follow their instructions you may feel pain, or you could have a hip dislocation.
- **CAUTION** - Attend all visits that your surgeon wants you to after your surgery to check your hip and how it is working. Have the x-rays requested by your surgeon. The visits and x-rays help to determine if there are any problems with the bones around your hip, or any problems with R3 delta Acetabular System implant. Also, by attending all of your surgeon visits, any problems that you have can be treated, which may keep them from becoming serious.

### ***What are the risks of having this surgery?***

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

- possible chipping, cracking, or breaking of the ceramic acetabular liner or femoral head during or after surgery (If this happens during surgery, your surgery may last longer because the ceramic part that has broken needs to be replaced. If this happens after surgery, you may have to have a second surgery to replace the parts that are damaged.)
- creation of ceramic wear particles (Wear particles or debris can travel to other parts of the body where it may cause an unwanted reaction requiring more treatment.)

- squeaking or other noise produced by the hip joint during activity (The squeaking or noise may be bothersome or it may mean that there is a problem with your hip replacement.)

In addition to the complications listed above, any type of hip replacement surgery has the risk of complications. These include, but are not limited to, the following:

- creation of wear particles (debris) from any of the parts of the implant (Wear particles or debris can travel to other parts of the body where it can potentially cause an unwanted reaction requiring further treatment.)
- fracture or breaking, movement (migration), loosening, or dislocation of the hip implant requiring revision surgery to take out some or all of the parts of the hip replacement
- pain
- broken bones during or after implantation of the prosthesis (This may mean the surgeon has to fix the broken bone during surgery, you may not be able to have the implant, or you may need another surgery.)
- an allergic reaction to implant materials (You may have a skin rash, hip pain, or need the implant removed.)
- excessive bleeding (You may need to have a blood transfusion.)
- nerve damage (You may have difficulty feeling your skin in parts of your leg or in moving your foot.)
- leg length change (One leg may be longer than the other which may cause you to limp. You may need a special shoe to help correct this.)
- blood clots ( These clots usually happen in the leg and may cause leg pain or leg swelling. A piece of the clot may move to your lungs which can cause death.)
- bruising or a collection of blood around the incision (This may cause pain or may need to be drained/removed.)
- wound healing problems
- wound infections
- periarticular calcification (You may have bone form around your hip joint which may cause pain or problems moving your hip.)
- heart attack

- “stomach” or bowel problems (You may feel sick to your stomach or have trouble having a bowel movement after surgery.)
- Urinary problems (You may have trouble urinating or you may get a bladder infection.)
- decreased ability to move the hip
- worsening of other joint or back conditions (Other joints may become stiff or sore after surgery.)
- reactions to anesthesia (You may feel sick to your stomach, your mouth may feel dry, your throat may be sore, or you may feel sleepy or cold. Rarely serious reactions to anesthesia happen and can cause death.)
- pneumonia (You may have a hard time breathing, a cough, and/or fever. This can usually be treated with medicine(antibiotics) but can be serious and result in death.)
- death

The harms listed for each complication above are not a complete list of all possible harms that can happen with each complication. Your surgeon will discuss with you all of the risks that are associated with the use of the R3 delta Acetabular System and total hip replacement surgery with you.

### ***What are the benefits of having this surgery?***

Good results after hip replacement surgery are not guaranteed, but hip replacement surgery may help you resume a more active life and may reduce pain and improve the motion in your hip joint.

The results of a study of the R3 delta Ceramic Acetabular System in patients who had hip replacement surgery are included in the next section called “*What are the results of studies of the R3 delta Ceramic Acetabular System?*” These results describe the benefits these patients experienced.

## ***What are the results of the study of the R3 delta Ceramic Acetabular System?***

A study of the R3 delta Ceramic Acetabular System was completed and included the results of 137 R3 delta Ceramic Acetabular System hip surgeries from five different locations in Europe. In this study, the R3 delta Ceramic Acetabular System was compared to another total hip replacement system that included a liner and femoral head made of different materials than the R3 delta Ceramic Acetabular System. Patients were examined before surgery (preoperatively) and at 3 months, 1 year and 3 years after surgery (postoperatively).

This study was limited to patients who had non-inflammatory degenerative joint disease (NIDJD) and were between 18 and 75 years of age. Therefore, the safety and effectiveness of the R3 delta Ceramic Acetabular System has not been determined in patients requiring hip replacement for reasons other than non-inflammatory degenerative joint disease or patients not between the ages of 18 and 75.

### **Safety Information**

#### Adverse Events

For a summary of the adverse events related to the R3 delta Ceramic Acetabular System in this study, see the section titled “What complications have been reported with the R3 delta Ceramic Acetabular System?”

#### Revision

One patient had to have surgery to take out an implant by the 3-year follow-up visit. The implant was removed due to a femoral fracture (broken thigh bone) and none of the hip socket (acetabular) parts were revised.

#### Radiographic Examination

Patients had x-rays taken immediately following surgery, and at 1 and 3 years following surgery. X-rays at 3 years following surgery were checked for loss of bone around the implants and/or movement of the implants (femoral or acetabular). Such findings may result in the implants working poorly and/or the need for revision. The X-rays 3 years after surgery showed four out of 116 (3.4%) patients had evidence of significant movement of one of the implants .

### **Effectiveness Information**

#### Modified Harris Hip Score

The Modified Harris Hip Score collects information on how the hip feels and works by asking the patient about their pain, how well they can complete daily activities like walking, sitting, and putting on shoes and socks, and assessing how much they can move their hip. Each response gets a certain number of points depending upon how you answer. Point totals are from 0 to 100. 100 is the best score indicating no pain, no limitations in how you perform your daily activities, and normal motion of the hip, and 0 is the worst score indicating that you have significant pain, poor ability to perform your daily activities, and poor motion at the hip. A Modified Harris Hip Score from 90 to 100 is considered excellent, 80 to 89 is considered good, 70 and 79 is considered fair, and below 70 is considered poor. At three years after their surgery, there were 84 patients who had excellent scores, 17 patients who had good scores, 4 patients who had fair scores and 6 patients who had poor scores.

Modified Harris Hip Scores were collected before surgery (preoperatively) and at each follow-up visit after surgery (postoperatively). The average score improved from 47.9 points before surgery to 92.0 points after surgery at the 3-year visit. This indicates that patients had less pain, improved their ability to complete activities of daily living, and/or move their hips after surgery.

#### WOMAC Score

The Western Ontario and McMaster Universities Arthritis Index (WOMAC) is a list of questions completed by patients to see how they judge their pain, ability to perform daily activities, and hip stiffness. The WOMAC scoring goes from 0 (worst) to 96 (best). An increased total WOMAC score after hip surgery means a patient had improvement in pain, decreased stiffness and/or improved ability to perform activities of daily life. The average WOMAC score increased from 37.8 points before surgery to 88.6 points at 3 years after surgery.

#### UCLA Activity Level Rating

The UCLA score is an activity level questionnaire completed by patients. The UCLA score goes from Level 1 (wholly inactive, dependent on others, cannot leave residence) to Level 10 (regular participation in impact sports). An increased UCLA score indicates increased patient activity. The average UCLA score improved from 3.6 before surgery to 6.1 at 3 years after surgery. (Level 3=Sometimes participates in mild activities such as walking, limited housework, and limited shopping, Level 4=Regularly participates in mild activities, Level 5=Sometimes participates in moderate activities, such as swimming, or could do unlimited housework or shopping, and Level 6= Regularly participates in moderate activities)

***What complications have been reported with the R3 delta Ceramic Acetabular System?***

A study of 137 patients who had R3 delta Ceramic Acetabular System hip surgery was completed and the tables below show the reported complications, or adverse events, that were noted as related to the R3 delta Ceramic Acetabular System.

During surgery (intraoperatively), the following adverse events were noted as related to the R3 delta Ceramic Acetabular System.

<b>Description of adverse events related to the use of the R3 delta Ceramic Acetabular system during surgery</b>	<b>Total number of patients for whom this adverse event was reported out of the total number of hips in the study</b>	<b>Percent (%) of patients who had this adverse event</b>	<b>Treatment or testing needed due to this adverse event</b>	<b>Number of patients needing this treatment or testing</b>
Thigh bone break	1 out of 137	0.7%	During the hip surgery, a wire was wrapped around the thigh bone to hold it together	1
Leg length change	1 out of 137	0.7%	Needed a shoe that was tall enough to make the shorter leg the same length as the other leg	1

After surgery (postoperatively), the following adverse events were reported as related to the R3 delta Ceramic Acetabular System.

Description of adverse events related to the use of the R3 delta Ceramic Acetabular System that happened after surgery	Total number of patients who reported this adverse event out of the total number of hips in the study	Percent (%) of patients who had this adverse event	Treatment or testing needed due to this adverse event	Number of patients needing this treatment or testing
Irritation or swelling of body parts around the hip	7 out of 137	5.1%	Needed medicine taken by mouth and/or injected into the hip	4
			Needed medicine taken by mouth and physical therapy	1
			Needed medicine or a special shoe to help the hip	1
			None	1
Hip Pain	6 out of 137	4.4%	Needed an x-ray	1
			None	5
Thigh bone break	4 out of 137	2.9%	Needed another surgery to wrap wire around the bone to hold the bone together	1
			Needed another surgery to replace the metal shaft (stem)	1

			Needed medicine or a special shoe to help the hip	1
			None	1
Groin or leg pain	4 out of 137	2.9%	Needed medicine	1
			Needed to return to the hospital and get medicine injected into the hip	1
			None	2
Elevated metal ions	3 out of 137	2.2%	None	3
Limp	3 out of 137	2.2%	Needed a special shoe to help the hip	1
			None	2
Weakness in hip	1 out of 137	0.7%	None	1
Nerve related adverse event	1 out of 137	0.7%	None	1
Hip slips out of place (hip subluxation)	1 out of 137	0.7%	None	1
Leg length change	2 out of 137	1.5%	Needed a shoe that was tall enough to make the shorter leg the same length as the other leg	2

### ***How to decide about having this treatment***

Discuss the possible risks and benefits associated with this surgery and any other possible treatments for your hip problems with your surgeon and with your family or caregiver to decide if this is the right treatment for you.

*Date of issue xx/xx/xxxx*

### ***What other treatments are there?***

Although your surgeon is considering the use of the R3 delta Ceramic Acetabular System for a hip replacement, you should know that there are potentially other treatments for your hip problem. Other treatments that you and your surgeon will likely choose from are listed below:

- No treatment. With this choice, your surgeon will continue to observe your hip for worsening of symptoms such as pain and/or loss of the ability of the hip joint to work normally.
- Exercise, medication, a hip brace or a combination of any of these treatments.
- Hip fusion surgery that surgically connects the femur (thigh bone) to the pelvis (hip) causing the two bones to heal together to become one.
- Total hip replacement with another implant or implant parts made of different materials. Choices include a metal femoral head and a plastic liner, a ceramic femoral head and plastic liner, or another hip replacement system that has a ceramic ball and ceramic liner.

## ***What happens before, during and after the surgery?***

### Before Surgery (Preoperative):

Follow your surgeon's or other treating physician's instructions. When patients are given a date for surgery, they often receive instructions and information to explain all the steps that need to be done before the total hip replacement. Ask your surgeon to provide such written instructions about what to do and what not to do before and following total hip replacement.

Tell your surgeon if you think you have an infection (tooth abscess, cold, flu, bladder infection) because your surgery may need to be moved to a later date.

Make sure that someone takes you and drives you home from the hospital. For the first few weeks after surgery you will need help with household chores like cooking, cleaning, shopping and bathing. If you do not have anyone to help you tell your surgeon.

### During Surgery (Intraoperative):

In preparation for surgery, your anesthesiologist (the person who puts you to sleep and provides drugs or other agents to cause the feeling of pain to be blocked) will examine you. You can ask the anesthesiologist any questions before the actual surgery.

The hair around your hip may be shaved to reduce the risk of infection. You may also be given pills or an injection to calm you before the operation. You will then be taken into the operating room where you will be given an anesthetic (drug to put you to sleep and /or prevent you from experiencing any pain during the surgery) before your surgery. The surgery usually takes between 1 and 2 hours to complete, but may be longer.

Your surgeon will make a cut (incision) in the skin near your hip. Then cartilage and bone will be taken from your femur (thigh bone) and acetabulum (socket), Figures 5 and 6, so that the artificial replacement ball and socket implants may be put in the bone. Your surgeon will implant the ball and socket joint (that has been sized to fit your body), make sure it fits, and close the incision, Figures 7 through 9.



Figure 5. Hip before Surgery



Figure 6. Hip after Surgeon Removes the Bone before Inserting the Implants



Figure 7. Metal Shell and Ceramic Liner Inserted



Figure 8. Hip Stem Inserted into Femur and Ball Head Attached

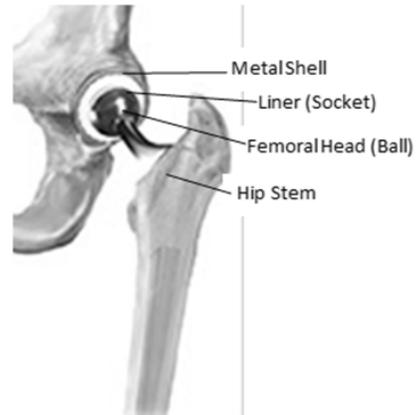


Figure 9. Total Hip Replacement

### After Surgery (Postoperative)

Immediately after surgery you will be moved to the recovery room to be checked on by nurses and your doctor. When you wake up from surgery, your leg that was operated on may be swollen and bruised and your muscles may be stiff and sore. You may be given pain medications to take regularly while you are healing. When you wake up fully you will be taken to your hospital room.

Your surgeon and/or hospital staff will tell you about any limitations for moving your legs and body while in or out of bed. You will probably 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 extra fluid from the space around your hip (some blood and clear liquid).
- You will experience mild to severe pain after surgery, but your surgeon will provide medicine to control your pain.
- The hospital will probably provide you with special stockings and/or medication to reduce the risk of blood clots (thickening of the blood).

Most hip replacement patients will be in the hospital three to five days and then be sent either home, or to another place where they can be taken care of while they heal. You may be in the hospital longer, depending on your condition and your progress in rehabilitation.

In the days and weeks following surgery:

- Your surgeon will decide how much weight you will be able to put on the operated hip (this will determine how active you can be during rehabilitation).
- You will use canes, crutches, or a walker to help you to reduce the weight on your hip.
- Have someone help you walk to the toilet or perform other activities of daily living so that you do not fall.
- Follow your surgeon's advice about how much, and in what directions, you may or may not move your hip and leg.
- Make sure you have a date for all follow-up visits with your surgeon and make sure you show up for all of them. During these visits, x-rays of your hip may need to be done to see if there are any problems such as a broken bone, a broken implant, or changes in the position of the implant. X-rays will also check the progress of bone healing around the implant.

### ***Are there things I should do when I travel?***

Implants that go in your body, including hip replacement implants, may activate metal detector alarms like the ones at airport security checks. Tell the security person about your artificial hip. Ask your surgeon if he can provide you with a card that says that you have had a hip replacement. This can be used if a metal detector alarm is activated.

### ***When should I call the surgeon after surgery?***

Call your surgeon if you experience any of the following symptoms:

- Signs of infection such as fever, chills, redness around your incision, increased pain, the feeling of pressure in the hip, or difficulty walking. Infection can cause an implant to fail, which would require you to have a second surgery to take out the hip implants.
- Bleeding or excessive drainage (continued oozing of liquid) from your incision(s) that is more than what your surgeon told you to expect. Too much bleeding or drainage may be a sign that your wound is not healing properly and you need to have the surgeon examine it. You may need to take medicine, or you may need to have the incision re-opened to make sure it will heal correctly.
- Severe pain that comes on quickly or an increase in your pain level that limits being able to perform daily activities. This kind of pain may indicate that there is a problem with your hip replacement and you should call your surgeon to see if he/she thinks you should be examined.
- Loss of feeling or your feeling is dull or numb in your leg/foot. This may indicate that there is a problem with your hip replacement and you should call your surgeon to see if he/she thinks you should be examined.

### ***Where can I go to find out more information?***

This document is provided to give you information about your treatment choices. It is not intended to replace advice from a doctor. If you have any further questions or need additional information about the R3 delta Ceramic Acetabular System, speak with your surgeon.

The company that makes the R3 delta Ceramic Acetabular System is:

Smith & Nephew, Inc.

1450 Brooks Road

Memphis, TN 38116

800-238-7538 (within continental U.S.A.)

901-396-2121 (all international calls)