

MAKOplasty® Robotic Arm Assisted Total Hip Replacement  
**Your Pre-operative Guide**



MAKOplasty® Total Hip Replacement is indicated for adults who suffer from non-inflammatory or inflammatory degenerative joint disease. It is a truly patient-specific procedure planned and performed from a 3-D model of your hip. MAKOplasty is enabled by the surgeon-controlled RIO® Robotic Arm Interactive Orthopedic System, which helps your surgeon achieve optimal implant placement so you can return to an active lifestyle.



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The information provided herein is not meant to substitute for the in-depth consultation you should have with your physician. Only a licensed physician can adequately diagnose and explain your underlying orthopedic condition, the natural history of the condition without intervention, the MAKOplasty procedure, medically acceptable alternative procedures, and the potential complications and risks of any procedure and/or operation. In every case your physician must guide you on all aspects of your surgery, including pre- and post-operative care. Individual results will vary.

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# Understanding Degenerative Joint Disease

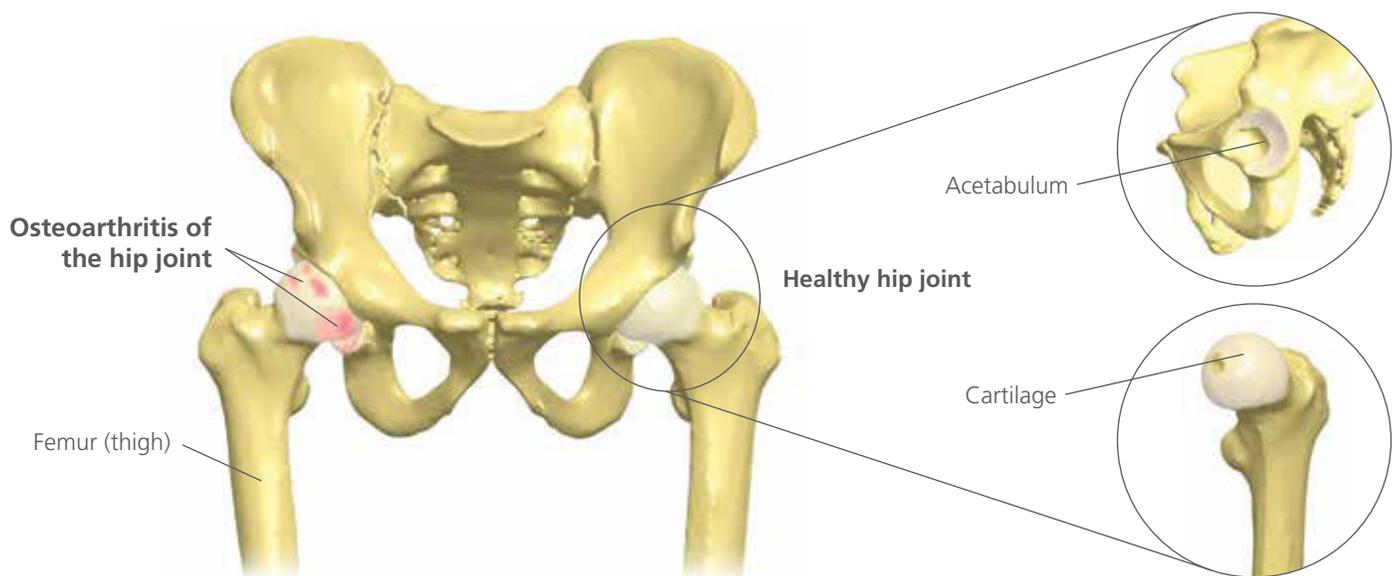
The hip is one of your body's largest weight-bearing joints. The hip is called a ball-and-socket joint because the spherical head of the thigh bone (femur) moves inside the cup-shaped hollow socket (acetabulum) of the pelvis. These bones are covered by cartilage, a layer of firm, elastic tissue that cushions the bones and allows smooth, easy movement of the joint.

## What is degenerative joint disease (DJD) of the hip?

There are different types of DJD that may cause hip pain. These include but are not limited to:

- **Osteoarthritis (OA):** The most common type of hip arthritis, called "wear-and-tear arthritis" because the cartilage wears down over time. As the protective cartilage wears away, bare bone is exposed and bone-on-bone contact occurs.
- **Post-traumatic arthritis:** Results from a severe fracture or dislocation of the hip
- **Rheumatoid arthritis (RA):** An inflammatory arthritis of the joints
- **Avascular necrosis (AVN):** A condition where the "ball" or femoral head has lost a healthy supply of blood flow causing the bone to die and the femoral head to become misshapen
- **Hip dysplasia:** A developmental deformation or misalignment of the hip joint

## Anterior (front) view of the pelvis



# Understanding Hip Arthritis Pain



## Hip Arthritis Pain Symptoms

Pain can occur in the following places:

- Groin
- Buttock
- Outside the hip
- Sacroiliac joint area of the back
- Thigh

Pain from the hip may be mistaken for back pain, and may be treated as such until the diagnosis of hip arthritis is made.

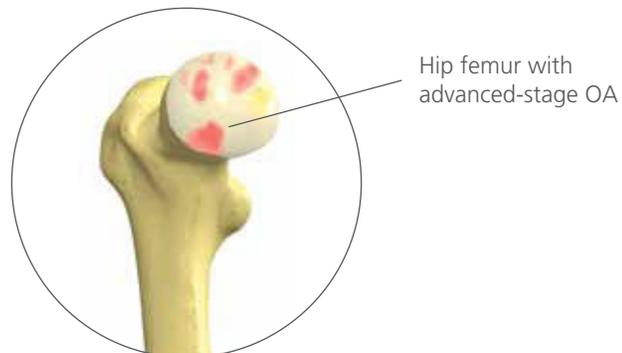
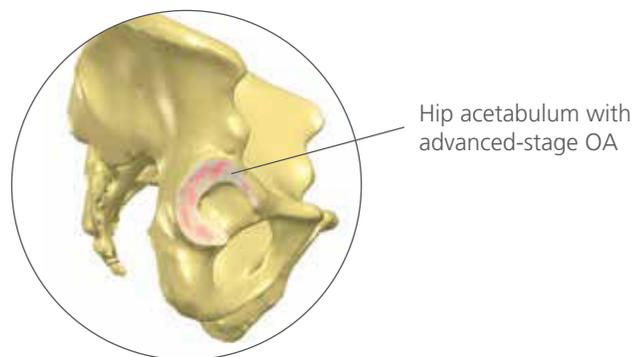
As hip arthritis progresses and pain increases, with minimal or no relief from non-surgical treatments, your doctor may recommend total hip replacement.

### What is the main symptom of hip arthritis?

The main symptom of hip arthritis is pain. The pain may not only be in the hip, but it may radiate down into the front of the thigh. Pain may be present only during activities, such as walking, or it may occur all the time. Range of motion may also be affected.

### What causes the pain?

As arthritis progresses and cartilage wears away, small flakes of it are absorbed by the capsule — the soft tissue envelope that surrounds the hip joint. The absorption of the cartilage flakes causes inflammation and pain. When the cartilage is entirely worn away, the ball-and-socket bones touch, creating bone-on-bone contact. This contact creates mechanical pain, swelling, and stiffness for which anti-inflammatory drugs or injections provide only transient pain relief.



# Total Hip Replacement

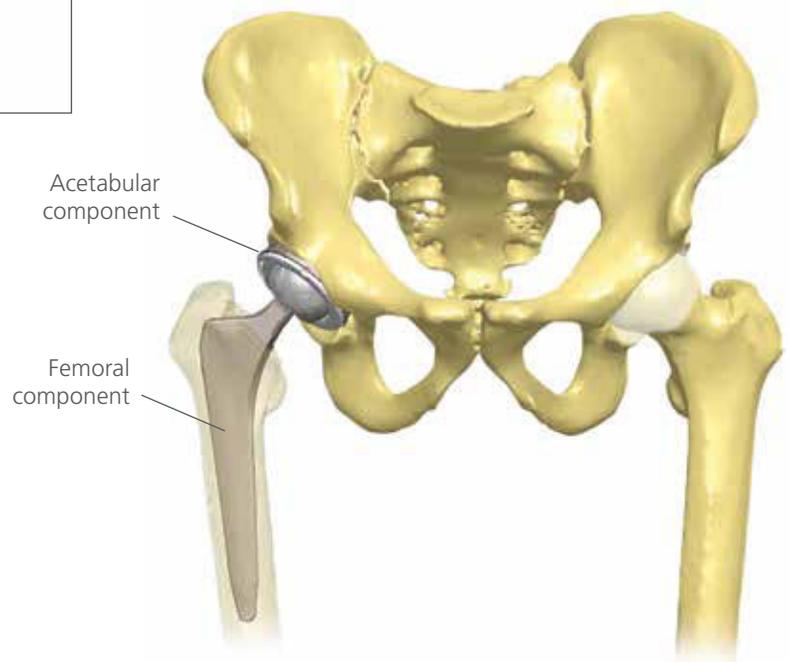
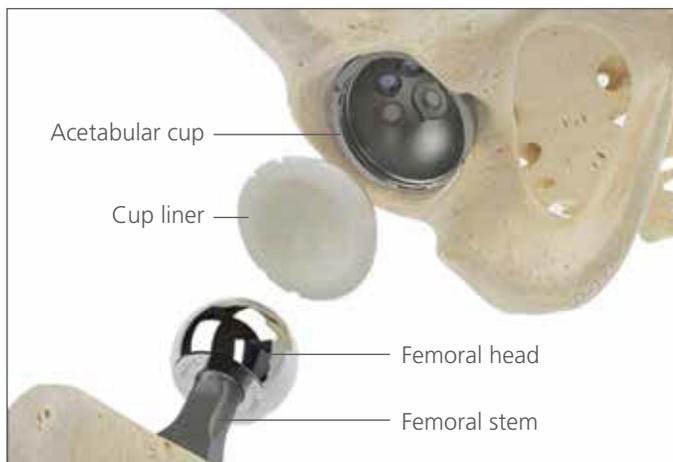
## What is total hip replacement?

Total hip replacement, also referred to as total hip arthroplasty, is a surgical procedure in which the ball-and-socket of the hip joint are replaced by implants as shown in the image below.

- A metal cup with a plastic liner replaces the socket in the pelvis
- A metal or ceramic head, attached to a metal stem implanted in the femur, replaces the ball

The new femoral head and cup liner provide a smooth bearing surface allowing the joint to move smoothly. The cup and stem are implanted in the bone, and have a surface that allows the bone to grow into the implant for permanent fixation. These materials have demonstrated durability if implanted in the correct position.

## Components of a hip replacement



### Why do some hip replacements fail?

Hip replacements can fail for a number of reasons. Since implants are mechanical devices, they are subject to mechanical failure if given the right conditions. The most common reason for implant failure is loosening. Loosening can be caused by wear of the plastic liner, creating debris, or it is sometimes the result of infection. Another reason for hip replacement failure is joint instability or dislocation.

Dislocation is the most common short-term complication, frequently occurring in the first year after surgery. Other issues that can arise with hip replacement are fracture of the bones holding the implants, and a difference in length of the operative leg compared to the opposite leg. Implants that are not placed in the proper orientation can impinge or come in contact with each other, the pelvis, or the femur.

Biological failure is another reason for hip replacement failure. This includes the risk of infection, either at the surgical area or in the bloodstream. In hospitals that report their results, infection risk averages 0.88%. This failure rate can vary, so you should ask your doctor the risk in his/her hospital. Patients with a compromised immune system are at greater risk. Tell your doctor if you suffer from diabetes, rheumatoid arthritis, cancer, excessive alcohol or drug use, or if you are a smoker.



X-ray of implanted hip replacement components



X-ray of a dislocated hip following hip replacement

# MAKOplasty® Total Hip Replacement

MAKOplasty is surgeon-controlled robotic arm assisted total hip replacement. Here's how it works:

## Pre-surgical planning

If your surgeon determines that you are a good candidate for MAKOplasty, he or she will schedule a CT scan of your hip prior to surgery. The RIO® system creates a virtual model of your hip from the CT scan, and a patient-specific surgical plan is created for optimal implant size and placement, based on your unique anatomy.

## Registration and intra-operative guidance

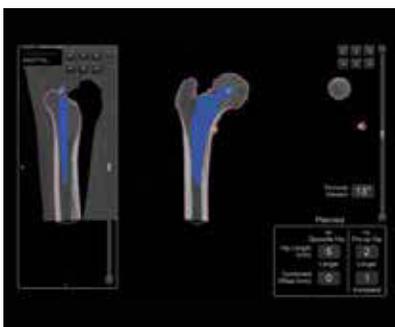
The surgical procedure starts with a registration process, so that the RIO system can physically track the hip's position and match it with the virtual model on its computer. A tracker with arrays is placed in the top of your hip. It collects constant, real-time information on your hip's physical location and passes it to the RIO system via a high-definition camera.

Once your hip is registered, the RIO system provides visualization and measurements that help your surgeon optimize implant positioning and alignment. If necessary, he or she can adjust the surgical plan. Once the plan is finalized, a safety zone is established for the use of the surgeon-controlled robotic arm.

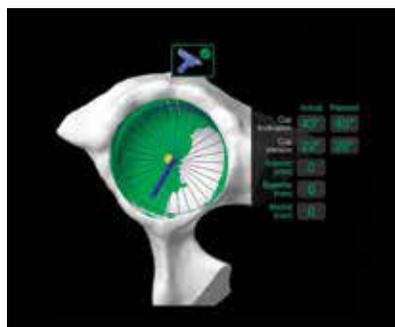


RIO Robotic Arm Interactive  
Orthopedic System

## MAKOplasty hip procedure



Patient-specific planning for  
femoral stem placement



Precision reaming of the  
acetabular cup



Surgical results summary



**Acetabular cup system with femoral head**

## Your Implant

The RESTORIS® Family of Hip Implants are used for MAKOplasty procedures with the RIO system. MAKOplasty enables a new level of accuracy in hip replacement, and is designed to enhance stability and increase range of motion.



### Robotic arm assisted cup placement

The surgeon utilizes the robotic arm to prepare and shape the pelvic bone in the acetabular socket for the metal cup implant, in a process called reaming. While the surgeon leads this process, the RIO system provides the surgeon visual, auditory, and tactile feedback to enforce the safety zone established in the surgical plan for optimal bone preparation.

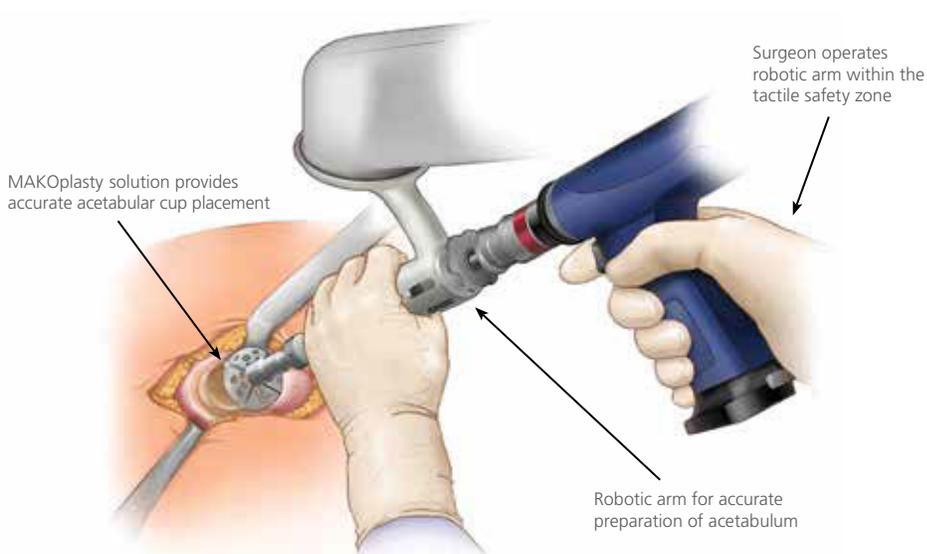
When bone preparation is complete, the cup is implanted using the robotic arm to assure placement is accurate in terms of depth and orientation. The plastic liner is then locked into the metal cup.

### Guided femoral bone preparation

The RIO system enables guided femoral neck resection and femoral bone preparation, providing the surgeon with real-time data on positioning and hip length. This step of the procedure may be done before or after the cup placement.

### Final Steps

Once bone preparation is complete, the femoral stem is implanted in the thigh bone, and the femoral head is attached to the stem to reconstruct leg length and soft tissue tension. The femoral head is placed in the cup, and the RIO provides the surgeon all the information needed to confirm the operation was completed as planned.



# MAKOplasty® Benefits



A successful total hip replacement reduces pain, improves mobility, and enables patients to return to their activities of daily living. MAKOplasty helps the surgeon place the implants in the desired orientation, providing a good, stable biomechanical reconstruction and accurate leg length restoration.

## What are the clinical benefits of robotic arm assisted MAKOplasty Total Hip Replacement?

MAKOplasty Total Hip Replacement is enabled by the RIO® Robotic Arm Interactive Orthopedic System, and provides a level of accuracy and reproducibility unattainable with conventional hip replacement procedures.

Accurate placement and alignment of implant components are critical for a successful hip replacement. Published studies show even an experienced surgeon can be off by more than just a few degrees in judging the cup and stem implant positions using conventional techniques.<sup>1</sup> A study conducted at Massachusetts General Hospital<sup>2</sup> evaluated more than 1,800 conventional total hip replacements and found that 53% of the cup implants were not optimally positioned. If the placement of the cup and stem are off by too much, the error can lead to mechanical failure and complications like dislocation or reduced range of motion.<sup>3,4</sup>

Early clinical data suggests that MAKOplasty demonstrates 4-6 times greater accuracy in cup implant placement than manual techniques in laboratory settings, reducing chances for complications such as impingement (rubbing together), implant wear, and dislocation.<sup>5</sup>

Additionally, a single-surgeon study evaluating 300 patients with total hip replacements also found that robotic arm assisted MAKOplasty resulted in more accurate implant placement compared to manual surgery. The increased accuracy appeared to be correlated with lower early dislocation rates.<sup>6</sup>

1. Dorr LD, Wan Z, Malik A, Zhu J, Dastane M, Deshmone P. A comparison of surgeon estimation and computed tomographic measurement of femoral component anteversion in cementless total hip arthroplasty. *J Bone Joint Surg Am.* 2009;91:2598-2604.
2. Callanan MC, Jarret B, Bragdon CR, et al. The John Charnley Award: Risk factors for cup malpositioning; Quality improvement through a joint registry at a tertiary hospital. *Clin Orthop Relat Res.* 2011;469:319-219.
3. Jolles BM, Zangger P, Leyvraz PF. Factors predisposing to dislocation after primary total hip arthroplasty: A multivariate analysis. *J Arthroplasty.* 2002;17.3:282-288.
4. Clohisy JC, Calvert G, Tull F, McDonald D, Maloney WJ. Reasons for revision hip surgery: A retrospective review. *Clin Orthop Relat Res.* 2004;429:188-192.
5. Nawabi DH, Conditt MA, Ranawat AS, Dunbar NJ, Jones J, Banks SA, Padgett DE. Haptically guided robotic technology in total hip arthroplasty – a cadaveric investigation. *Proc Inst Mech Eng H.* 2013 Mar227(3):302-9.
6. Ilgen R. Robotic assisted total hip arthroplasty improves accuracy and clinical outcome compared with manual technique. 43rd Annual Advances in Arthroplasty Course. October 22-25, 2013, Cambridge, MA.

# After Surgery

## Physical therapy

As early as one to two days after surgery, a physical therapist may meet with you and help you move from your hospital bed to a chair to improve your blood flow and circulation. As you recover, your therapist may also ask you to work on simple exercises to strengthen your muscles to improve the mobility of your hip. When you are more stable, your physical therapist may help you out of bed for a short walk with a walker or crutches. As your body heals, you should be able to graduate from a walker to crutches and then a cane for support until you can put your full body weight on your hip.

Your post-surgical physical therapy program should continue shortly after your return home, and be conducted under your physician's guidance and supervision. A typical physical therapy program following hip surgery includes exercises that tighten the muscles around the hip in order to regain your mobility as soon as possible. Your therapist can show you appropriate ways to accommodate your daily lifestyle while you are recovering.

Your surgeon will be in charge of determining when you will be able to return to work, drive a car, or do low-impact aerobic exercises such as walking or swimming. Jogging and high-impact sports are not recommended. You should follow your surgeon's instructions and advice post-surgery.

## Recovery at home

You may want to prepare your home before your surgery so it will be comfortable and safe when you return from the hospital. Think safety first by removing any hazards including floor rugs, loose phone lines or cables and clutter that can cause you to slip or fall. Organize the items you'll need on a daily basis within arm's reach to reduce unnecessary movement during the first few days following your return home.

According to the Arthritis Foundation (2009), the success of your surgery also relies on how well you follow your surgeon's post-operative instructions. Rest when you need to, but moving about frequently with your cane, crutches, or walker, according to your surgeon's instructions, will gradually increase your activity level to help you heal and feel better.

- With your surgeon's approval, practice walking every day, first around your home and later outside.
- You should be able to resume most light activities within six to eight weeks with your physician's approval.
- It is important to follow the exercise program developed by your physical therapist diligently. This will help your muscles regain mobility and strength, allowing you to walk normally again.

## Ask Your Doctor About Self Care

- Before your surgery, arrange for assistance you may require from others after surgery.
- Eat a balanced diet, take any vitamin or iron supplement your doctor recommends and be sure to drink plenty of fluids. Good nutrition may help your tissue heal and your muscles regain strength.
- Work with your physician to monitor the healing of your hip replacement. It's important to keep your physician and prescribed therapy appointments.



Patient Name: \_\_\_\_\_  
Date of Implant: \_\_\_\_\_  
Site of Implant:  Left Hip  
(check all that apply)  Right Hip  
Surgeon Name: \_\_\_\_\_  
Hospital: \_\_\_\_\_  
Address: \_\_\_\_\_  
Phone Number: \_\_\_\_\_

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