

YOUR SURGEON'S

# choice of implants

FOR YOUR SURGERY

*C2a-Taper*<sup>TM</sup>  
ceramic-on-ceramic articulation



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## Your Surgeon Has Chosen the C2a-Taper™ Acetabular System

The purpose of the C2a-Taper™ Acetabular System is to reconstruct diseased and/or damaged hips using ceramic devices to replace the bone surfaces in total hip joint replacement. This type of surgery is intended to reduce or relieve pain and/or improve hip function.

### Who is a candidate for the C2a-Taper™ Acetabular System?

- Patients having their first total hip joint surgery
- Patients with the diagnosis of non-inflammatory degenerative joint disease:

**Osteoarthritis** - the breakdown of cartilage (rubbery tissue that pads the joints) in your joint causing painful rubbing together of your hip bones.

**Avascular necrosis** - a loss of blood supply to the hip bones causing a change in shape of the bones.

**Congenital hip dysplasia** - dislocation of the hip at birth due to abnormal development of the hip joint.

**Traumatic arthritis** - inflammation (swelling, redness, and pain) of the joint caused from an injury or damage characterized by breakdown of the bone and cartilage (rubbery tissue).

- Patients whose bones have stopped growing.

## When is this system NOT to be used (contraindications)?

- If you have an infection of any kind, even if it is not near your hip surgery site.
- Patients with inflammatory degenerative joint disease such as rheumatoid arthritis characterized by joint stiffness and sometimes deformity.
- If you previously had total hip surgery and are requiring another surgery (called a revision).
- Patients whose bones have not stopped growing.
- Patients with poor quality of bone, ligaments, tendons, or muscle (soft tissue) surrounding the hip.
- Patients with vein, artery, muscle, or nerve disease.

## Clinical Studies:

A prospective, multi-center clinical study was performed in the United States on a ceramic hip system similar to the C<sup>2</sup>a-Taper™ Acetabular System. The system studied included the exact same ceramic components (head and liner) used in the C<sup>2</sup>a-Taper™ Acetabular System.

A total of 965 procedures in 854 patients (some patients had procedures on both right and left hips) were performed. Six procedures were excluded from the analysis, therefore, the primary analysis sample included 959 procedures in 848 patients. This study included 12 sites with 19 surgeons participating. All patients were having their first hip replacement surgery and follow-up data was collected at the immediate post-operative, 6, 12, and 24-month post-operative intervals. In general, patients improved after receiving the ceramic hip system by having less hip joint pain, better function and increased range of motion at 6 months post-operative or later. Eleven devices out of the 959 primary procedures enrolled in the study have been revised or removed. These results are comparable to other hip systems on the market.

## What are the risks and benefits?

While there can be no guarantee of success, benefits can include the potential relief of pain and return of normal function of the hip. There is also the possibility for this ceramic bearing replacement to outlast the standard replacements currently being used.

The risks and complications associated with this hip replacement are expected to be similar to those of other hip replacements. Each of these complications can occur during and/or after surgery and may require medical treatment including additional surgery.

- Although rare, allergic reactions to the implant material have been reported following hip surgery. The presence of any implant material can be seen as foreign and the body tissue may react against the implant.
- Infection can lead to failure of the hip joint.
- Nerve damage has been reported as a result of having hip surgery.
- Dissolving of the bone (osteolysis) around an implant may cause loosening of the implant resulting in failure of the hip joint.
- Particles of hip implant materials, bone cement, and bone are produced by contact between hip implant parts and hip implant parts and bone. These particles may cause a tissue reaction and implant loosening.
- During surgery a hole or break in the bone may occur while inserting the device.
- Loosening or movement of the implants can occur when the implants are no longer firmly attached. This can be due to trauma, poor placement of implants, bone dissolving, and/or excessive activity.
- Abnormal hardening of tissue around the joint can occur which may or may not decrease movement of the joint.
- Inadequate hip range of motion due to improper selection or positioning of components.
- Undesirable shortening of the leg.
- Complete or partial movement of the joint from its normal position due to improper attachment and positioning. Loosening of muscle and other connective tissue can also contribute to these conditions.
- Implants can break when they are no longer firmly attached to bone or due to strenuous activity, poor placement, trauma, improper fracture healing, or excessive weight.
- Worn areas can occur where the two ceramic components rub on each other.
- Wear and/or change of shape of ceramic joint surfaces have been reported following total hip replacement.
- A piece of the thighbone can pull away (trochanteric avulsion) or broken bone may not heal properly as a result of muscle stress, early weight bearing, or inadequate reattachment.
- Problems of the knee or ankle on the treated side or opposite side due to changes in leg position, or poor quality muscle.
- Intra-operative or post-operative broken bone and/or post-operative pain.
- Breaking of ceramic heads have been reported in other systems.
- Death associated with hip surgery and/or surgery in general.

## **What should I expect after surgery?**

There are limits to what you can do after your hip surgery. You will need to protect your hip from full weight bearing until adequate healing has occurred. After healing has occurred any strenuous activity (such as playing basketball, football, or heavy physical work) or trauma can cause your procedure and/or your implants to fail.

Total hip joint replacement devices reduce pain and restore function for many patients. While these devices are generally successful they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue. These devices can break or become damaged as a result of strenuous activity, trauma or even normal use, and may need to be replaced at some time in the future. Please read and comply with the follow-up care and treatment instructions given to you by your doctor.

## **What are possible complications during or shortly after surgery?**

- Pain.
- Femoral or acetabular perforation (hole in hip parts) during surgery.
- Broken bone during placement of the implant during surgery.
- Damage to blood vessels.
- Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.
- Undesirable shortening or lengthening of the leg caused by improper selection of the implant size.
- A breaking down of the joint tissue (traumatic arthrosis) of the hip from intra-operative positioning of the leg.
- Blood clots in the veins or lungs, or a heart attack.
- Pocket of blood caused by bleeding from a broken blood vessel which appears "black and blue."
- Early wound healing problems.
- Infection.
- Complete (dislocation) or partial movement (subluxation) of the joint from its normal position.

## **What kinds of problems can happen later?**

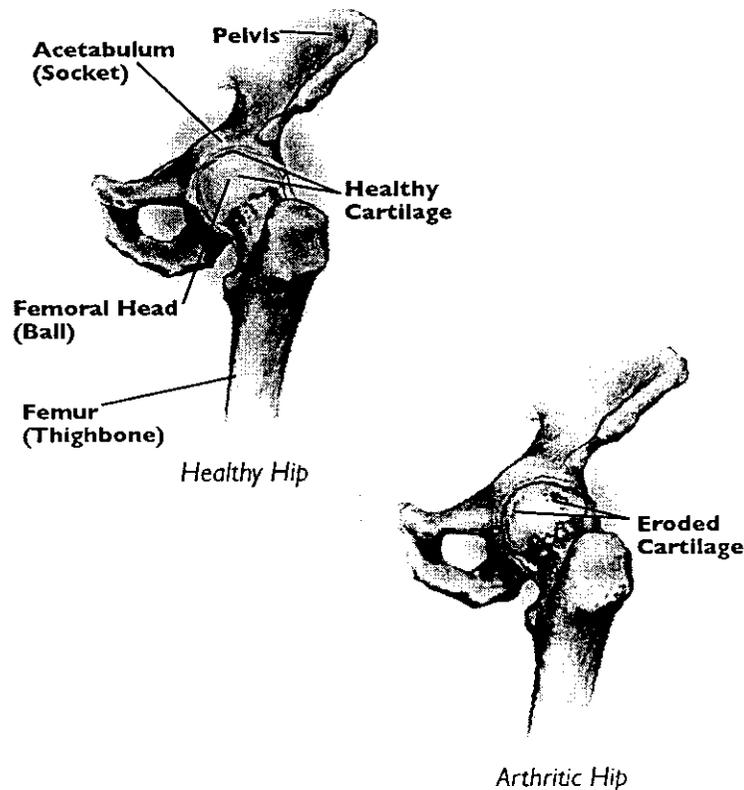
- Pain.
- Infection.
- Loosening, movement, and/or breakage of the implants can occur when

the implants are no longer firmly attached. This can be due to trauma, poor placement of implants, bone dissolving, and/or excessive activity.

- Abnormal hardening of tissue around the joint which may or may not decrease movement of the joint.
- Inadequate hip range of motion due to improper selection or positioning of components.
- Undesirable shortening of the leg.
- Complete or partial movement of the joint from its normal position due to improper attachment and positioning. Loosening of muscle and other connective tissue can also contribute to these conditions.
- A piece of the thighbone can pull away (trochanteric avulsion) or broken bone may not heal properly as a result of muscle stress, early weight bearing, or inadequate reattachment.
- Delayed wound healing.

## The Hip

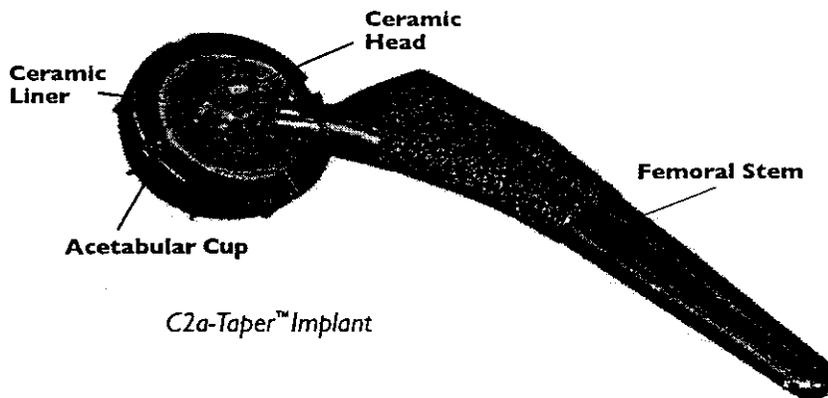
A total hip replacement removes the arthritic ball (femoral head) of the upper thighbone (femur), as well as, the damaged cartilage from the hip socket (acetabular). See the following pictures of a healthy hip and an arthritic hip. The arthritic hip has lost some of the tough connective tissue called cartilage.



## Description of the Device

The C2a-Taper™ Acetabular System is a ceramic on ceramic hip articulating system meaning that both surfaces that provide movement of your new hip joint are made of a hard ceramic material. These surfaces include a ceramic ball (or head), and a rounded surface called a liner. The liner sits in an acetabular cup and the ceramic ball moves around in the ceramic liner providing movement in your hip. The ceramic liner fits into the cup which is placed in your acetabulum (socket bone).

Along with the metal acetabular cup, this system also includes a metal femoral stem. The ceramic head fits on top of the stem, which is placed down the center of the thighbone.



## Call your doctor if you experience any of the following:

- If you see redness, swelling or drainage in or around your incision;
- If you have an unexplained fever (temperature over 100° Fahrenheit or 38° centigrade) or chills that last more than a day;
- If you have severe hip pain that is not relieved by your pain medicine;
- If you have unusual shortening of your leg or unusual turning at your hip joint; or
- If you have sudden swelling in your thigh or calf. Failure to notify your doctor when experiencing any of the above signs or symptoms, could lead to symptoms worsening.

## What are alternative treatments?

Depending on individual circumstances, alternative procedures may include the use of other commercially available total hip replacement devices. In addition, non-surgical treatment such as reduced activity and/or pain medication or other surgical treatments that do not involve the use of a device may be considered.

## What might increase the risk of failure?

- Patients who are unable to follow instructions given by medical professionals.
- Noticeable bone loss, severe decreased bone mass (osteoporosis).
- Disorders that interfere with the body's ability to absorb nutrients, which may slow bone formation.
- Softening of the bones (osteomalacia).
- Conditions associated with poor wound healing (severe diabetes, chronic pressure ulcers, severe protein deficiency and/or poor nutrition).
- Allergic reaction to an implant material.

NOTE: When material allergy is suspected, appropriate tests should be performed prior to implant selection for your surgery.

## Implant Removal

Request that your implants be returned to Biomet Inc. (Biomaterials Dept.) at the following address, if all or part of the implants are removed for any reason.

## Further information

Your doctor should be able to answer any questions you may have regarding the C2a-Taper™ Acetabular System and the potential use of this device for treatment of your hip. You may also contact Biomet, Inc., the manufacturer of this device.

Caution: Federal Law (USA) restricts this device to sale, distribution or use by or on the order of a physician.

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