# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glossary of Terms</td>
<td>4</td>
</tr>
<tr>
<td>Background information</td>
<td>6</td>
</tr>
<tr>
<td>What is the CERAMAX® Ceramic Total Hip System?</td>
<td>7</td>
</tr>
<tr>
<td>What type of patient is right for the CERAMAX® Ceramic Total Hip System?</td>
<td>7</td>
</tr>
<tr>
<td>What type of patient is not indicated for the CERAMAX® Ceramic Total Hip System?</td>
<td>8</td>
</tr>
<tr>
<td>What are the warnings and precautions for the CERAMAX® Ceramic Total Hip System?</td>
<td>9</td>
</tr>
<tr>
<td>What are risks with the CERAMAX® Ceramic Total Hip System?</td>
<td>10</td>
</tr>
<tr>
<td>What adverse events have been reported?</td>
<td>12</td>
</tr>
<tr>
<td>How can ceramic artificial hip joints fail?</td>
<td>14</td>
</tr>
<tr>
<td>What are potential benefits of the CERAMAX® Ceramic Total Hip System?</td>
<td>15</td>
</tr>
<tr>
<td>What can you do to prepare yourself for surgery?</td>
<td>16</td>
</tr>
<tr>
<td>How is hip replacement surgery performed?</td>
<td>17</td>
</tr>
<tr>
<td>What problems may occur during your surgery?</td>
<td>17</td>
</tr>
<tr>
<td>What can you expect after your operation?</td>
<td>18</td>
</tr>
<tr>
<td>When should I call the doctor after surgery?</td>
<td>19</td>
</tr>
<tr>
<td>What alternatives do you have?</td>
<td>19</td>
</tr>
<tr>
<td>What can you do to improve your recovery?</td>
<td>19</td>
</tr>
<tr>
<td>What do the clinical studies show?</td>
<td>20</td>
</tr>
<tr>
<td>Important safety information</td>
<td>22</td>
</tr>
<tr>
<td>User assistance information sources</td>
<td>22</td>
</tr>
<tr>
<td>How long will my implant last?</td>
<td>23</td>
</tr>
<tr>
<td>Are there instructions for when you travel?</td>
<td>23</td>
</tr>
</tbody>
</table>
GLOSSARY OF TERMS

**Acetabulum**: Hip socket.

**Adverse**: Harmful or unfavorable.

**Anesthetic**: Drug used to eliminate the feeling of pain.

**Anesthesiologist**: A physician who is specialized in the practice of anesthesiology, the branch of medicine involving the use of drugs or other agents that cause the feeling of pain to be blocked.

**Artificial joint**: Artificial parts used for replacing a hip joint.

**Avascular Necrosis**: A condition that results in death of the bone due to loss of blood supply. When this condition happens in the hip, it often results in a decay of the bone in the femoral head (the top part of the thighbone) because of too little or no blood flowing to it.

**Bearing**: The bearing is the area of interaction between the moving parts of the joint replacement implant. For a hip joint replacement implant it’s where the ball and the liner meet. Bearing materials can be made out of metal, ceramic or plastic.

**BIOLOX® delta**: A zirconia-alumina, ceramic composite matrix engineered to resist cracks and fractures.

**Bone cement**: A mixture formed by the chemical reaction of two chemical agents (a monomer and a polymer) that produces a grout-like material that is used for some joint replacement surgeries for attaching the joint replacement prosthesis to the surrounding bones. In some artificial hip joint replacement surgeries it can be used in the thigh bone (femur) and/or the socket bones (acetabulum).

**Calcification**: Hardening of the tissue.

**Cemented use**: An implant that is used with bone cement. (See Bone cement definition)

**Composite diagnosis**: Term used when combining two or more similar diagnoses or conditions into one diagnosis or condition.

**Degenerative joint 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.

**Dislocation**: When the moving parts of the joint slip out of position. This term applies to both the patient’s own joint, as well as artificial joint. (See Hip Dislocation definition)

**Femoral**: Related to the thighbone (femur).

**Femur**: Thighbone.

**Fixation**: The stabilization (connection) of an implant to surrounding bone or cement.

**Hematoma**: A localized swelling filled with blood.

**Hip dislocation**: When the head of the femur (thighbone) slips out of the socket bones (pelvis) of the hip joint. This problem that can also occur with an artificial hip joint replacement device whereby the ball head of the device separates from the socket of the device.

**Hip joint**: A ball and socket joint consisting of a rounded femoral head or “ball” that fits into a cup or “socket” to allow movement between the thigh bone and the hip bone (pelvis).

**Hip replacement**: When an artificial or man-made ball and socket device replaces the patient’s own hip joint.

**Hip revision**: Replacement of an artificial hip device with a new artificial hip device (this may be required for a broken or failed device or an infection).

**Immunosuppressed**: A condition where the patient’s immune system is not as effective as normal.

**Impingement**: Excessive pressure is placed on the tissue around the hip device.

**Intraoperative**: During the time of the surgery.

**Metal ions**: Metal atoms with a positive or negative charge.
**Migration:** A complication resulting from a movement of the artificial joint replacement device from its original position. When the femoral device and/or the acetabular device changes position within the surrounding bones following hip joint replacement surgery.

**Myocardial Infarction:** A heart attack.

**Noncemented use:** An implant that is used without bone cement. (See Bone cement definition)

**Noninflammatory degenerative joint disease (NIDJD):** A general term used to describe a damaged hip joint from osteoarthritis, avascular necrosis and/or post-traumatic arthritis.

**Operative site:** The part of the body being operated on.

**Osteoarthritis:** A loss of bone and cartilage that may lead to joint pain and stiffness.

**Osteolysis:** The loss of calcium in the bone.

**Osteomyelitis:** Inflammation of the bone due to infection; can be a complication of surgery or injury, although infection can also reach bone tissue through the bloodstream. Both the bone and the bone marrow may be infected.

**Osteonecrosis:** A loss of blood supply to the bones characterized by changed shape and increased thickness of the bone, a flattening of the joint surface (See also Avascular Necrosis definition).

**Osteoporosis:** A loss or weakening of bone.

**Physiotherapy:** Therapy that uses physical agents such as exercise, massage.

**Postoperative:** The period following surgery.

**Post-traumatic arthritis:** Arthritis caused by a serious injury to the joint.

**Precaution:** Less severe than warnings and inform about a non-life threatening hazard that is associated with a device. (See Warning definition.)

**Primary joint replacement:** Replacement of the natural joint with an artificial joint.

**Pyogenic:** Producing pus (commonly a site of infection or foreign material in the body).

**Pulmonary Embolism:** Blood clot in the lung.

**Rehabilitation:** Exercise that is prescribed by a doctor following joint replacement surgery to help improve the healing process and overall function of the joint that was replaced with an artificial joint.

**Revision:** Replacement of a failed device with a new device.

**Rheumatoid arthritis:** A condition in which the body’s immune system begins to attack the tissue surrounding the joint leading to joint pain, stiffness and inflammation.

**Skeletally immature:** The bones of the skeleton are still growing.

**Slackness:** Not tight, taught, firm or tense; looseness or laxity. The affected joint feels unsteady and “catches” or “slips” as it moves.

**Systemic:** Pertaining to the whole body

**Traumatic arthritis:** A condition that results in loss of bone and cartilage in the joint after a physical injury.

**Trochanteric bursitis:** Swelling of the large sacs that separate the hip bones from the muscles and tendons of the thighs and buttocks. This results in tenderness on the upper, outside portion of the thigh bone.

**U.S. Food and Drug Administration (U.S. FDA):** The government agency that regulates medical devices in the United States.

**Venous Thrombosis:** Blood clot in the veins.

**Warning:** Serious and life threatening circumstances that are associated with a device.

**Wear resistance:** Ability to withstand or resist wearing out of parts of the joint that are in contact with each other as they move. This term applies to both the patient’s own joint and to an artificial joint.
BACKGROUND INFORMATION

The hip joint allows movement to occur between the thigh bone (femur) and the hip bone (pelvis). The pelvis contains a “socket”, which is called the acetabulum. The ball-shaped head of the femur fits into the acetabulum, forming a “ball and socket joint” that allows the leg to have a wide range of movements such as walking and squatting.

There are many conditions that can develop in the hip joint that may make it necessary to have a hip replacement. Some of the more common conditions include:

**Osteoarthritis:** A slow loss of bone and cartilage in the hip joint that may include the abnormal formation of bone and cartilage around the joint, leading to pain and stiffness.

**Avascular Necrosis:** A condition that results in death of the bone in the femoral head (the ball part of the thigh bone) due to loss of blood supply. A decay of the bone in the femoral head (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 cartilage in the hip joint after a physical injury.

Due to the similarities between these conditions patients can expect the same outcome regardless of which one of these diagnoses they have, so they are normally grouped into a single category termed, “noninflammatory degenerative joint disease”, or NIDJD. There are several treatment alternatives available for NIDJD. Your doctor has discussed these with you and has advised that you consider replacement of your hip joint with an artificial hip joint device, also known as a total hip replacement prosthesis.
WHAT IS THE CERAMAX® CERAMIC TOTAL HIP SYSTEM?

There are many artificial hip joint devices available in the United States. The following is a description of one kind of artificial hip called the CERAMAX® Ceramic Total Hip System. The CERAMAX® Ceramic Total Hip System is intended for treatment of the noninflammatory degenerative joint disease (NIDJD) condition just described.

The CERAMAX® Ceramic Total Hip System is a ceramic-on-ceramic bearing total hip replacement prosthesis system. The system consists of five parts:

- **Femoral Head**
  The femoral head is made from an alumina composite matrix ceramic material called BIOLOX® delta.

- **Ceramic Insert**
  The ceramic insert is named CERAMAX® and is made from the same BIOLOX® delta alumina composite ceramic matrix material as the femoral head.

- **Acetabular Shell**
  A metal cup made from titanium alloy. Some acetabular shells are designed to allow for bone screws and some are not.

- **Bone Screws**
  The metal screws are made from titanium alloy.

- **Femoral Stem**
  The metal femoral stem is made from titanium alloy.

The BIOLOX® delta femoral head component replaces the top of your thighbone and is attached to the metal stem component. The metal stem fits into your thigh bone without the use of bone cement (non-cemented fixation). The CERAMAX® insert is assembled to the metal acetabular shell which is secured to your hip socket without the use of bone cement (non-cemented fixation). Depending on which acetabular shell your surgeon chooses for you, bone screws may or may not be used to anchor the shell in place (adjunctive fixation). The BIOLOX® delta femoral head attached to the top of the metal stem in your thigh bone moves against the CERAMAX® insert within the acetabular shell in your hip socket to allow for movement of your hip.

The CERAMAX® Ceramic Total Hip System is the only hip system currently approved by the U.S. Food and Drug Administration and available in the U.S that utilizes BIOLOX® delta for the ceramic femoral heads and the acetabular liners.

WHAT TYPE OF PATIENT IS RIGHT FOR THE CERAMAX® CERAMIC TOTAL HIP SYSTEM?

(Indications for Use)

The CERAMAX® Ceramic Total Hip System can be used in patients that are:

- Skeletally mature
- Diagnosed as having noninflammatory degenerative joint disease (NIDJD) which is a general term used to describe a damaged hip joint from osteoarthritis, avascular necrosis and/or post-traumatic arthritis,
- Their own hip joint (primary hip replacement surgery)
- The condition of their hip bones allows for the metal parts of the artificial hip implant to be inserted without bone cement (noncemented fixation)
WHAT TYPE OF PATIENT IS NOT INDICATED
FOR THE CERAMAX® CERAMIC TOTAL HIP SYSTEM?

(Contraindications)

You should NOT receive a CERAMAX® Ceramic Total Hip System if you have any of the following conditions:

• Skeletally immature, since the leg bones of their skeletons are still growing and presence of the artificial joint could cause shortening of the leg;

• Evidence of active infections that may spread to other areas of the body (e.g., osteomyelitis, pyogenic infection of the hip joint, overt infection, urinary tract infection, etc.) which could lead to infection within the hip that has the artificial joint, thereby requiring that it be removed;

• The presence of any known neoplastic (tumor-causing) or metastatic (spread of cancerous cells) disease which could negatively affect the outcome, especially if chemotherapy, radiation or other treatments are required for treating these conditions;

• Significant neurologic or musculoskeletal disorders or diseases that may adversely affect gait, weight bearing or postoperative recovery (e.g., muscular dystrophy, multiple sclerosis) which may compromise the patients’ rehabilitation therapy following their joint replacement surgery;

• Presence of highly communicable disease(s) that may limit follow-up (e.g., immuno-compromised conditions, hepatitis, active tuberculosis, etc.) and could increase in duration and/or severity after the surgery;

• Any condition that may interfere with postoperative recovery e.g., Paget’s disease (a bone disorder), Charcot’s disease (a neurologic disorder) and could significantly compromise patient rehabilitation resulting in an unsatisfactory or poor functional outcome;

• Inadequate bone stock to support the device (e.g., severe osteopenia or osteoporosis) which could lead to movement (migration) or loosening of the hip joint device components within the surrounding bone(s) or result in a fracture of the bone(s) and/or the implant;

• Poor skin coverage around the hip joint which could lead to an infection of the surgical wound;

• Known allergies to the artificial hip implant materials which could lead to an allergic reaction by the tissues surrounding the hip joint and/or allergic reactions in other areas away from the hip;

• Marked atrophy (muscle and/or tissue loss) or deformity in the upper femur such as a birth defect affecting the leg bones which could significantly compromise patient rehabilitation following the surgery and/or result in an unsatisfactory or poor functional outcome;

• Inflammatory degenerative joint disease (such as rheumatoid arthritis) which was not approved by the Food and Drug Administration for treatment with this device;

• Joint instability that cannot be corrected and could result in a dislocation of the artificial joint or reduced or complete loss of patient mobility.

Your doctor will need to review your overall health to determine whether the CERAMAX® Ceramic Total Hip System is appropriate. You should inform 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 bone strength in the future.
WHAT ARE THE WARNINGS AND PRECAUTIONS FOR THE CERAMAX® CERAMIC TOTAL HIP SYSTEM?

**Warnings**

Be aware that the artificial hip joint can fail (does not function as it was designed to do) if there are extreme stresses placed on it. Failures may be from the type of work performed, such as heavy labor. Failure may also occur if you are considered extremely overweight or suffer from a physical or a mental condition that causes you to fall.

If the artificial joint fails, you will need to have a second operation to have it removed from their hip.

**Precautions**

There are limitations with any artificial hip joint and it is important for you to listen and follow your surgeon’s recommendations. Some precautions include:

- **DO NOT** put excessive weight on the hip joints immediately after surgery.
- **DO NOT** attempt to move the hip joint more than what was told by the surgeon.
- **DO** follow the instructions given about exercising the hip joints prior to and after surgery.
- **DO** tell the surgeon if there are changes in overall health after surgery, such as running a temperature, drainage or an odor coming from the surgical wound or an increase in the amount of pain experienced at the hip.

Failure to take the appropriate precautions **COULD** increase the length of time it takes for your recovery and **COULD** result in being dissatisfied with the outcome of your hip replacement surgery.
WHAT ARE RISKS WITH THE CERAMAX® CERAMIC TOTAL HIP SYSTEM?

Most of the risks associated with hip replacement with the CERAMAX® Ceramic Total Hip System are expected to be similar to those of other artificial hip replacements; however, there are some risks that are only with the CERAMAX® Ceramic Total Hip System. Each of these reactions or complications with the CERAMAX® Ceramic Total Hip System or with other hip replacements can occur during and after surgery and may require medical intervention (such as more surgery) and removal of the artificial hip implant. Once implanted, the functional life of any hip replacement system cannot be predicted. To reduce the risk for failure (the artificial hip does not function as it was designed to do), patients should discuss with their doctors what they should do prior to surgery and carefully follow any instructions given. The risks and complications only with the CERAMAX® Ceramic Total Hip System include:

- Chipping or cracking of the ceramic femoral head and/or ceramic insert components
- Wear of the ceramic acetabular components has been reported following total hip replacement. Wear may be from particles of metal, or other debris that can cause scratching of the surfaces of the parts that move against each other (bearing surfaces). Higher rates of wear may shorten the useful life of the artificial hip, and could lead to another surgery to replace the worn prosthetic components (revision surgery).
- Squeaking or other noises of the hip joint during activities such as walking. The significance of this occurrence is unknown.

The risks and complications with the CERAMAX® Ceramic Total Hip System and with other artificial hip replacements include:

- Femoral (thighbone) or hip bone (socket) fracture may occur while implanting the hip replacement device
- Particles of the hip replacement parts and bone may be generated by contact between the hip implant and bone. These particles may cause local responses such as bone breakdown, or they may move to other parts of the joint and cause painful tissue irritation. Particles in between the hip implant parts or between the hip implant and bone may cause more particles to form at an increasing rate and cause more breakdown of bone. Breakdown of bone can lead to having to remove or replace the hip implant parts.
- Rarely, an artificial hip component can break as a result of improper assembly, trauma, strenuous activity, the component is in the wrong position, or it has gone past the functional life.
- One or more of the components can come apart. (Component dissociation.)
- Chronic inflammatory response due to metal sensitivity
- Potential for post-operative and continued joint pain
- Reduced function at the hip
- Damage to blood vessels resulting in hematoma (a localized swelling filled with blood)
- Temporary or permanent nerve damage resulting in pain or numbness of the affected limb
THE RISKS AND COMPLICATIONS WITH THE CERAMAX® CERAMIC TOTAL HIP SYSTEM AND WITH OTHER ARTIFICIAL HIP REPLACEMENTS INCLUDE (CONT’D):

- Undesirable shortening or lengthening of the leg treated with the artificial hip implant (leg length inequality)
- Cardiovascular disorders including venous thrombosis (blood clot in the veins), pulmonary embolism (blood clot in the lung), or myocardial infarction (heart attack)
- Temporary or permanent nerve damage
- Delayed wound healing
- Infection
- Migration (movement) or loosening of the hip implant, or partial or complete dislocation of the hip implant can result from improper positioning of the components or trauma (accidents).
- Undesirable bone formation or changes (ossification or calcification), with or without affecting joint mobility
- Inadequate range of motion due to improper selection or positioning of hip implants
- Death

COMMON REASONS FOR ARTIFICIAL HIP REPLACEMENT FAILURE

Many of these risks and others can cause the artificial hip implant to fail (does not function as it was designed to do), and it is not possible to identify each and every cause for failure. The most common reasons cited for failure of the artificial hip replacement surgery are:

- An infection that develops within the hip joint necessitating removal of the hip joint prosthesis
- The hip joint becomes loose from the bone caused by a fall
- An adverse bone reaction caused by particles coming from the implant
- A complete or a partial dislocation of the ball head and socket components causing the implant to be unstable
- Severe pain where the cause may or may not be known
- The tissues around the implant react adversely to particles coming from the implant
- The position of the hip prosthesis changes
- One or more of the device components breaks or the device comes apart (disassociates).
WHAT ADVERSE EVENTS HAVE BEEN REPORTED?

There were two investigational studies of the CERAMAX® Ceramic Total Hip System conducted in the U.S. The data and other information from those studies formed the basis for the approval by the U.S. Food and Drug Administration of the CERAMAX® Ceramic Total Hip System.

The first study investigated the CERAMAX® Ceramic Total Hip System with 28mm BIOLOX® delta femoral head components and 28mm CERAMAX® ceramic acetabular insert components and is called the 28mm CoC (ceramic-on-ceramic) study.

The second study investigated the 36mm the CERAMAX® Ceramic Total Hip System with 36mm BIOLOX® delta femoral head components and 36mm CERAMAX® ceramic acetabular insert components and is called the 36mm CoC (ceramic-on-ceramic) study.

Adverse events occurring in patients receiving the CERAMAX® Ceramic Total Hip System were compared to adverse events occurring in patients receiving a commercially available artificial hip joint having 28mm sizes of femoral head and acetabular insert sizes as part of the study. More information about these two studies can be found in the “What do the clinical studies show?” section of this Patient Guide brochure.

The following tables summarize the adverse events reported from each (28mm CoC and 36mm CoC) study that happened during and following the surgery for the CERAMAX® Ceramic Total Hip System.
The number of adverse events to patients that happened following the hip replacement surgery for the 36mm COC (Ceramic-on-Ceramic) investigational study.

<table>
<thead>
<tr>
<th>Descriptions of the Adverse Events After the Surgery</th>
<th>28mm COC Number of Patients</th>
<th>28mm COC Percentage of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceramic liner failed</td>
<td>1 out of 177</td>
<td>0.6%</td>
</tr>
<tr>
<td>Ceramic liner broke</td>
<td>1 out of 177</td>
<td>0.6%</td>
</tr>
<tr>
<td>Artificial hip dislocated</td>
<td>5 out of 177</td>
<td>1.2%</td>
</tr>
<tr>
<td>Inflammation of the tissues covering the upper thighbone (bursitis)</td>
<td>6 out of 177</td>
<td>3.4%</td>
</tr>
<tr>
<td>Breakdown of the bone (lysis)</td>
<td>1 out of 177</td>
<td>0.6%</td>
</tr>
<tr>
<td>Excessive bone formation around the artificial hip (heterotopic bone)</td>
<td>1 out of 177</td>
<td>0.6%</td>
</tr>
<tr>
<td>Femur part of artificial hip components became loose</td>
<td>3 out of 177</td>
<td>1.7%</td>
</tr>
<tr>
<td>Fracture of upper thighbone (trochanter)</td>
<td>2 out of 177</td>
<td>1.1%</td>
</tr>
<tr>
<td>Hip or thigh pain</td>
<td>4 out of 177</td>
<td>2.3%</td>
</tr>
<tr>
<td>Infection at or near the artificial joint</td>
<td>2 out of 177</td>
<td>1.1%</td>
</tr>
<tr>
<td>†Other adverse events</td>
<td>18 out of 177</td>
<td>10.2%</td>
</tr>
<tr>
<td>Surgical wound became infected</td>
<td>9 out of 177</td>
<td>5.1%</td>
</tr>
<tr>
<td>Weakness of hip muscles</td>
<td>5 out of 177</td>
<td>2.8%</td>
</tr>
</tbody>
</table>

†There were 18 other adverse events reported following the surgery for the 28mm COC study. In the 28mm COC study these 18 events were: Blisters (1); Damaged Nerve (1); Hip and/or thigh pain (2); Muscle Pain (2); Pain in the groin area (1); Pain after a fall (2); Pain in the thigh, buttock and calf (1); Patient Fell (1); Patient suffered physical injury (Trauma) (1); Patient’s surgical wound felt warm (1); Swelling caused by blood (Hematoma) (1); Swelling in the leg (1); Tendons in the hip and/or the leg that became inflamed (3).

The number of adverse events to patients that happened following the hip replacement surgery for the 36mm COC (Ceramic-on-Ceramic) investigational study.

<table>
<thead>
<tr>
<th>Descriptions of the Adverse Events Following The Surgery</th>
<th>36mm CoC Number of Patients</th>
<th>36mm COC Percentage of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceramic liner failed</td>
<td>1 of 168</td>
<td>0.6%</td>
</tr>
<tr>
<td>Ceramic liner broke</td>
<td>1 of 168</td>
<td>0.6%</td>
</tr>
<tr>
<td>Artificial hip dislocated</td>
<td>2 of 168</td>
<td>1.2%</td>
</tr>
<tr>
<td>Artificial hip partially dislocated (subluxation)</td>
<td>1 of 168</td>
<td>0.6%</td>
</tr>
<tr>
<td>Inflammation of the tissues covering the upper thighbone (bursitis)</td>
<td>17 of 168</td>
<td>10.1%</td>
</tr>
<tr>
<td>Excessive bone formation around the artificial hip (heterotopic bone)</td>
<td>3 of 168</td>
<td>1.8%</td>
</tr>
<tr>
<td>Femur part of artificial hip components became loose</td>
<td>1 of 168</td>
<td>0.6%</td>
</tr>
<tr>
<td>Fracture of upper thighbone (trochanter)</td>
<td>1 of 168</td>
<td>0.6%</td>
</tr>
<tr>
<td>Hip or thigh pain</td>
<td>6 of 168</td>
<td>3.6%</td>
</tr>
<tr>
<td>Infection at or near the artificial joint</td>
<td>2 of 168</td>
<td>1.2%</td>
</tr>
<tr>
<td>The artificial joint muscle and or bone problems</td>
<td>16 of 168</td>
<td>9.5%</td>
</tr>
<tr>
<td>*Other adverse events</td>
<td>14 of 168</td>
<td>8.3%</td>
</tr>
<tr>
<td>Pain (not specified)</td>
<td>8 of 168</td>
<td>4.8%</td>
</tr>
<tr>
<td>Skin condition</td>
<td>3 of 168</td>
<td>1.8%</td>
</tr>
<tr>
<td><strong>Squeaking or other noises coming from the hip</strong></td>
<td>15 of 168</td>
<td>8.9%</td>
</tr>
<tr>
<td>Stiffness of the hip</td>
<td>1 of 168</td>
<td>0.6%</td>
</tr>
<tr>
<td>Surgical wound became infected</td>
<td>6 of 168</td>
<td>3.6%</td>
</tr>
<tr>
<td>Weakness of hip muscles</td>
<td>4 of 168</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

*There were 14 other adverse events reported following the surgery for the 36mm COC study. In the 36mm COC study these 14 events were: Bruise (1); General Hip Pain (2); Patient Falls (3); Stiffness (1); Swelling caused by blood (Hematoma) (1); Tendons in the hip that became inflamed (6).

**15 patients with a 36mm COC device reported 17 noise related adverse events: squeaking (8); clicking (7); snapping (1); vibration (1).
Artificial hip joints can and do fail (does not function as it was designed to do), and there are many causes for these failures to happen. Depending on the how and when the failure happened, also called the failure mode, the effects on the patient (and caregivers) may vary. When designing the CERAMAX® Ceramic Total Hip System, the potential modes of failure were considered. While the risk for failure is considered to be low, and the probable benefit to patients outweighs the risk, a description of the failure, the cause for the failure and effects from the failure are summarized in the following table.

<table>
<thead>
<tr>
<th>Description Of The Failure</th>
<th>Probable Cause For The Failure</th>
<th>Probable Effect Of The Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceramic component breaks during the surgery</td>
<td>Wrong ceramic component or component not correctly assembled with the metal shell</td>
<td>Ceramic and metal components are replaced with new components and the surgery takes significantly longer</td>
</tr>
<tr>
<td>Ceramic component breaks after the surgery</td>
<td>Wrong ceramic component or component not correctly assembled with metal shell; trauma to hip such as a fall.</td>
<td>Hip joint pain and/or adverse tissue reaction surrounding the hip joint; another surgery needed to replace some or all of the artificial hip components.</td>
</tr>
<tr>
<td>Ceramic component does not fit into the metal shell during surgery</td>
<td>Wrong ceramic component or component not correctly assembled to the metal shell</td>
<td>Either the metal shell, ceramic component or both are replaced and the surgery takes significantly longer.</td>
</tr>
<tr>
<td>Ceramic component does not fit into the metal shell after the surgery</td>
<td>Wrong ceramic component or component not correctly assembled to the metal shell</td>
<td>Another surgery needed to replace some or all of the artificial hip components.</td>
</tr>
<tr>
<td>Femoral ball head comes out of the socket during surgery</td>
<td>Wrong ball head or ceramic liner component or the components were not correctly aligned.</td>
<td>Some or all of the artificial hip joint components are replaced and the surgery takes significantly longer.</td>
</tr>
<tr>
<td>Femoral ball head comes out of the socket after surgery</td>
<td>Wrong ball head or ceramic liner component or the components were not correctly aligned; trauma to hip such as a fall.</td>
<td>Hip joint functions poorly; another surgery needed to replace some or all of the artificial hip components.</td>
</tr>
<tr>
<td>Ceramic and/or metal particles in the hip joint after surgery</td>
<td>Wrong ball head or ceramic liner component, components were not correctly aligned or ceramic components chipped or scratched.</td>
<td>Hip joint pain and/or adverse reaction of the tissues surrounding the hip joint; another surgery needed to replace some or all of the artificial hip components.</td>
</tr>
</tbody>
</table>
WHAT ARE POTENTIAL BENEFITS OF THE CERAMAX® CERAMIC TOTAL HIP SYSTEM?

Hip replacement can help people resume routine movements of everyday life, like climbing stairs, tying shoes and getting up from a chair. While there is no guarantee of success, benefits of hip replacement may include pain reduction and regaining motion.

Your surgeon has decided that you will benefit from hip replacement surgery. The three most common materials used in artificial hip replacement devices are Ceramic-on-Ceramic (ceramic ball with a ceramic liner), Metal-on-Plastic (metal ball with a plastic liner) and Metal-on-Metal (metal ball with a metal liner). Each device type may decrease hip pain and improve function.

The CERAMAX® Ceramic Total Hip System is an option for patients that may allow for their return to activities in their everyday lives. It has been engineered with materials to optimize strength and durability and has been extensively tested in the lab and in clinical trials (studies done on humans).

While there is no conclusive evidence that supports the benefits to patients of the CERAMAX® Ceramic Total Hip System over other artificial hips, the clinical and laboratory testing have shown the CERAMAX® Ceramic Total Hip System to have less wearing of the components when compared to Metal-on-Plastic artificial hip components. Patients may benefit from the CERAMAX® Ceramic Total Hip System by having a more durable artificial hip that won’t wear out as quickly as a Metal-on-Plastic artificial hip. There are concerns with reports of serious adverse reactions in patients having Metal-on-Metal artificial hips. These adverse reactions are believed to be caused by the metal particles and/or metal ions coming from the metal bearing components. Patients may benefit from the CERAMAX® Ceramic Total Hip System compared to a Metal-on-Metal artificial hip replacement device because the CERAMAX® Ceramic Total Hip System uses ceramic bearing components instead of metal bearings.

You should discuss with your surgeon the possible risks and benefits of the CERAMAX® Ceramic Total Hip System compared to the risks and benefits of other types of artificial hip replacement devices.

As with all surgery, there are a number of things which the doctor and hospital staff will ask you to do to help the operation be successful. If you have any questions or concerns, ask your doctor or hospital staff.
WHAT CAN YOU DO TO PREPARE YOURSELF FOR SURGERY?

Your doctor may want you to meet the Physical Therapist (PT) before surgery. The PT may give you some tips on preparing your house for rehabilitation and how you should sleep, get out of bed, sit, stand, and walk following surgery. In addition, before you go to the hospital, there are several things you can do before surgery to help make your recovery easier.

- **Commit to the success of your surgery**
  Working as a team, you, your physician, physiotherapist and your family (or care giver) must adopt a positive attitude toward the success of your surgery. Together, you will gain a clear understanding of the common goals and expectations of the procedure.

- **Remain as active as possible**
  Remaining active while waiting for your surgery is an important key to the success of your surgery. Studies have shown that the stronger and more flexible you are before your operation, the quicker you will recover and more flexible you will be after the operation. Gentle exercise such as walking, range of motion exercises and swimming can help you to stay strong and flexible. **DO seek your doctor’s advice before beginning any exercise.**

- **Stop smoking**
  If you have not already done so, you should stop smoking at least four weeks before your surgery. This will help reduce the risk of complications during and after your surgery.

- **Make sure all infections are cleared up prior to the surgery**
  These include: tooth abscesses, bladder infections, infections such as leg ulcers, colds and the flu. This is because infections could spread through your body during the operation and infect your new replaced joint. **Therefore, DO tell your surgeon immediately if you suspect you have an infection, as your surgery may have to be rescheduled.**

- **Rearrange your furniture**
  Rearrange your furniture to create wide traffic paths and remove obstacles. Make it as easy and safe as possible to move around your home during your recovery.

- **Life after the operation**
  You will need to have someone available to drive you home after the surgery. Additionally, for the first few weeks following your surgery, you’ll need some help with typical household chores like cooking, cleaning, shopping, bathing, and doing laundry. If you don’t have a spouse, relative or friend who can help you with these tasks, your healthcare team can assist you in making arrangements (in advance) for someone to help you.
HOW IS HIP REPLACEMENT SURGERY PERFORMED?

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. This is an opportunity for you to ask any questions before the actual surgery. On the day of your surgery, it is usual for your doctor to ask you not to drink or eat anything. The area around your hip may be shaved of any hair to reduce the risk of infection. You may also be given tablets or an injection to relax you before the operation. This is known as a “pre-med”. You will then be taken into the operating room where you will be given either a general or a regional anesthetic prior to your surgery. The surgery may take between 1-2 hours to complete.

The surgical procedure for a ceramic-on-ceramic total hip replacement involves removing your diseased hip bone and replacing it with an artificial ceramic ball on a metal stem. The metal stem is inserted into your thighbone. After a special instrument shapes the hip socket, a metal shell is placed into the socket. A ceramic liner is then inserted into the shell which provides the bearing surface. Finally, a ceramic ball is placed onto the metal stem which is placed into the new socket.

WHAT PROBLEMS MAY OCCUR DURING YOUR SURGERY?

Please refer to the section in this brochure describing “What are the risks with the CERAMAX® Ceramic Total Hip System?” for a comprehensive listing of the risks for hip replacement surgery and review these with your surgeon prior to surgery.

While rare, some problems that can occur during the surgery include:

• Femoral (thighbone) or hip bone (socket) fracture may occur while implanting the hip replacement device chipping or cracking of the ceramic femoral head and/or ceramic insert components

• Damage to blood vessels resulting in hematoma (a localized swelling filled with blood)

• Temporary or permanent nerve damage resulting in pain or numbness of the affected limb Undesirable shortening or lengthening of the leg treated with the artificial hip implant (leg length inequality)

• Cardiovascular disorders including venous thrombosis (blood clot in the veins), pulmonary embolism (blood clot in the lung), or myocardial infarction (heart attack)

• Death
WHAT CAN YOU EXPECT AFTER YOUR OPERATION?

Immediately after your surgery, you will be moved to a post-operative recovery room for close monitoring. You may have one or two intravenous drips in your arm to introduce fluids and/or medication into your body. When you wake up from surgery, your affected leg 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 recovering.

When you are fully conscious, breathing well and your blood pressure and pulse are stable after surgery, you will be taken back to your hospital room. You may not feel like eating much at first, but it is important that you drink liquids.

Recovery from any operation varies from patient to patient and post-operative rehabilitation programs vary from hospital to hospital and surgeon to surgeon. The following is a general recovery timeline after surgery:

Day 1: Move about with physiotherapy and a walking frame

Day 2/3: Move about with physiotherapy and independently with crutches

Day 3/4: Move about with physiotherapy and independently with a cane

Day 4-6: Return home

DO follow your surgeon’s instructions carefully. Your surgeon will give you detailed post-operative instructions before you leave the hospital. It is important to follow your surgeon’s instructions so healing from surgery can occur as quickly as possible.

Ongoing Evaluation:

DO follow your doctor’s schedule for examinations after surgery. Routine examinations will include regular X-ray exams to look for any problems such as hip bone or implant breakage, implant position changes, or anything abnormal. X-rays will also check the progress of bone healing around the implants. Routine examinations may also include blood work and urine analysis.
WHEN SHOULD I CALL THE DOCTOR AFTER SURGERY?

Infection:
Contact your doctor if you experience any of the following signs of infection:
- Drainage and/or unusual odor from the surgical incision
- Fever/temperature above 100.4° F for two consecutive days
- Redness, swelling or increased pain at or near the surgical incision

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

- Pain or Instability:
  Some pain is normal and expected during your rehabilitation period, and the pain should slowly decrease in the six to 12 weeks following surgery. If you experience any serious, immediate, or constant hip pain, pressure, feelings of unsteadiness, or if you are suddenly unable to put weight on your hip after the surgical 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).
  - Delayed wound healing
  - Inadequate range of motion due to improper selection or positioning of hip parts
  - Undesirable shortening or lengthening of the limb caused by improper selection of hip implant size
  - Device-related noises, such as squeaking, clicking, popping or grinding
  - Cardiovascular disorders, including blood clots in the veins or lungs

WHAT ALTERNATIVES DO YOU HAVE?

Depending on individual circumstances, alternative procedures may include the use of other commercially available total hip replacement parts already approved or cleared by the U.S. FDA; non-surgical treatment such as reduced activity and/or pain medication; or other surgical treatments that do not involve the use of an implant such as a hip fusion. Additionally, your doctor can recommend nonsurgical therapy such as weight loss, mild exercise programs, physical therapy.

WHAT CAN YOU DO TO IMPROVE YOUR RECOVERY?

Be sure to protect the new artificial hip implants from too much stress after surgery and always follow your surgeon’s advice and instructions. To do this, you should avoid high level activity such as playing basketball or doing heavy physical work. **DO NOT participate in high impact activities such as running or jumping during the first year after your surgery.** These activities can cause broken bones, loosening of implant components, or early wear of the implants.

Generally, within 6 weeks after surgery, you may return to driving and to work. You should be able to return to normal activities within a few months of the surgery, including gardening, and other low impact activities.

Please read and comply with the follow-up care and treatment instructions given by the physician and always follow your surgeon’s advice on hip precautions. Following your surgeon’s instructions and advice will improve the chances for a successful outcome of your artificial hip replacement surgery and your satisfaction with the results.
WHAT DO THE CLINICAL STUDIES SHOW?

Two clinical studies were performed to evaluate the safety and effectiveness of the CERAMAX® Ceramic Total Hip System. The first study collected data on 177 patients with the 28mm size of CERAMAX® Ceramic Total Hip System and the second study collected data on 168 patients with the 36mm size CERAMAX® Ceramic Total Hip System. The results from both of these patient groups were compared to those from a group of patients receiving a standard total hip device, that is, a control device, having a ceramic-on-polyethylene (plastic) ball and socket articulation. This ceramic-on-polyethylene control group consisted of 87 patients for the comparison with patients having a 28mm CERAMAX® Ceramic Total Hip System; 74 of these same ceramic-on-polyethylene patients with large components were used for the comparison with patients having a 36mm CERAMAX® Ceramic Total Hip System.

28MM CERAMAX
CERAMIC TOTAL HIP SYSTEM STUDY

Safety Data

Complication (safety) information was collected from the entire group of 264 hips. (177 ceramic-on-ceramic, 87 ceramic-on-polyethylene). There were no statistically significant differences in the proportions of adverse events (postoperative systemic or operative-site, or intraoperative complications) between the CERAMAX® Ceramic Total Hip System patients versus the standard ceramic-on-polyethylene total hip system patients.

In other words, the overall complication rate and types of complications for the CERAMAX® Ceramic Total Hip System were similar to the types reported for the standard ceramic-on-polyethylene total hip system. The most common operative site complications were trochanteric bursitis, wound problems, dislocations and musculoskeletal adverse events.

The revision rate (the number of artificial hip implants that were either removed or replaced) between the CERAMAX® Ceramic Total Hip System and the standard total ceramic-on-polyethylene hip system was also similar. Four patients out of 177 CERAMAX® Ceramic Total Hip System patients required a revision of their hip replacement prosthesis system and two patients with standard total ceramic-on-polyethylene total hip prosthesis systems required revision of their ceramic-on-polyethylene total hip system.

Reasons for revision in the CERAMAX® Ceramic Total Hip System patients were: 1) infection 2) acetabular liner failure 3) implant loosening and 4) patient fall. The reason for revision in both of the standard ceramic-on-polyethylene total hip system patients was recurrent dislocation of the prosthesis.

There were no deaths directly related to the use of the device in the study.

Effectiveness Data

Effectiveness information was collected from the entire group of 264 hips. Harris Hip Total Scores were used to summarize clinical outcome. The Harris Hip Rating is a widely used numeric scoring system that tells doctors how well patients are functioning with their hip replacement device, including their ability to walk (with or without aid), the amount of movement in their hip (range of motion) and their level of pain. There are 100 points possible in the Harris Hip Rating system and the patient’s overall result is based on their score. A Harris score from 90 to 100 is rated as Excellent, 80 to 89 is rated as Good, 70 to 79 is rated as Fair and below 70 points is a Poor result.

Preoperatively, 171 of the CERAMAX® Ceramic Total Hip System patients (96.6%) had a “Poor” Harris Hip Total Score. Post-operatively, after 24 months, 145 of 164 CERAMAX® Ceramic Total Hip System patients (88.4%) that reported at this time had a “Good” or “Excellent” Harris Hip Total Score.

These same data were also collected from the group of patients that received the standard ceramic-on-polyethylene total hip system device. Preoperatively, 86 of the standard ceramic-on-polyethylene total hip system patients (98.9%) had a “Poor” Harris Hip Total Score. Post-operatively, after 24 months, 73 of 81 the standard ceramic-on-polyethylene total hip system patients (90.1%) that reported at this time had a “Good” or “Excellent” Harris Hip Total Score.
Effectiveness Data

Effectiveness information was collected from the entire group of 242 hips. Harris Hip Total Scores were used to summarize clinical outcome. The Harris Hip Rating is a widely used numeric scoring system that tells doctors how well patients are functioning with their hip replacement device, including their ability to walk (with or without aid), the amount of movement in their hip (range of motion) and their level of pain. There are 100 points possible in the Harris Hip Rating system and the patient’s overall result is based on their score. A Harris score from 90 to 100 is rated as Excellent, 80 to 89 is rated as Good, 70 to 79 is rated as Fair and below 70 points is a Poor result.

Preoperatively, all 168 of the CERAMAX® Ceramic Total Hip System patients (100%) had a “Poor” Harris Hip Total Score. Post-operatively, after 24 months, 143 of 159 CERAMAX® Ceramic Total Hip System patients (90.0%) had a “Good” or “Excellent” Harris Hip Total Score.

These same data were also collected from the group of patients who received the standard ceramic-on-polyethylene total hip system. Preoperatively, 73 of the standard ceramic-on-polyethylene total hip system patients (98.6%) had a “Poor” Harris Hip Total Score. Post-operatively, after 24 months, 63 of 71 standard ceramic-on-polyethylene total hip system patients (88.7%) had a “Good” or “Excellent” Harris Hip Total Score.

Safety Data

Complication (safety) information was collected from the entire group of 242 hips. (168 ceramic-on-ceramic, 74 ceramic-on-polyethylene) With the exception of noise related adverse events, there were no statistical differences in the proportions of adverse events (postoperative systemic or operative-site, or intraoperative complications) between the CERAMAX® Ceramic Total Hip System patients versus the standard ceramic-on-polyethylene total hip system patients. There were 15 CERAMAX® Ceramic Total Hip System patients who were reported to have noise complications. Some of these noise related complications were deemed by the surgeon to be possibly related to the CERAMAX® Ceramic Total Hip System.

The revision rate (the number of artificial hip implants that were either removed or replaced) between the CERAMAX® Ceramic Total Hip System patients versus the standard ceramic-on-polyethylene total hip system patients was similar. Three patients out of 168 CERAMAX® Ceramic Total Hip System patients required revision of the CERAMAX® Ceramic Total Hip System and two patients required revision of the conventional total ceramic-on-polyethylene hip system. Reasons for revision in the CERAMAX® Ceramic Total Hip System patients were: 1) infection 2) ceramic liner fracture and 3) implant loosening. The reason for revision in both standard ceramic-on-polyethylene total hip system patients was recurrent dislocation of the prosthesis.

There were no deaths directly related to the use of the device in the study.
WHAT DO THE CLINICAL STUDIES SHOW?

Limitations Of The Studies

The two studies of the CERAMAX® Ceramic Total Hip System were limited to patients having a specific diagnosis of noninflammatory degenerative joint disease (NIDJD) in only one hip, as well as other specific criteria including age, weight and activity levels. Use of the CERAMAX® Ceramic Total Hip System was restricted to patients who came under these criteria that were defined in the study protocol. Therefore, the safety and efficacy of the CERAMAX® Ceramic Total Hip System for patients with conditions other than those that were defined by the study plan has not been established.

IMPORTANT SAFETY INFORMATION

Every surgery has risks and benefits. The performance of total hip replacement depends on your age, weight, activity level and other factors. There are potential risks, and recovery takes time. People with conditions limiting rehabilitation should not have hip replacement surgery. Only an orthopaedic surgeon can tell if total hip replacement is right for you.

Any time after your operation, if a physician prescribes an MRI scan for you, DO inform your physician that the CERAMAX® Ceramic Total Hip System has not been evaluated for safety and compatibility in the MR environment.

USER ASSISTANCE INFORMATION SOURCES

Discuss any questions regarding your hip surgery and the CERAMAX® Ceramic Total Hip System with your surgeon. For further information regarding the CERAMAX® Ceramic Total Hip System, you may also contact the manufacturer:

DePuy Orthopaedics, Inc.
700 Orthopaedic Dr.
Warsaw, IN 46582
www.depuy.com
1-800-366-8143

For more information about hip replacement please visit www.hipreplacement.com
HOW LONG WILL MY IMPLANT LAST?

The functional life expectancy of an artificial hip to remain attached within the hip joint, how long it will take for it to wear out and the how the tissues will react with time to any particles that are shed by the implant is not clearly known at the present time. It is a possibility that some or all of the components may need to be removed from your hip and replaced with other components at some point in the future.

ARE THERE INSTRUCTIONS FOR WHEN YOU TRAVEL?

As with many other medical implants and devices, your hip replacement implant may activate metal detector alarms such as those at airport security checks. **DO tell the security attendant about your artificial hip.** Ask your surgeon to provide you with a card to present that explains that you have had a hip replacement if a security device alarm is activated.
Limited Warranty and Disclaimer: DePuy Synthes Joint Reconstruction products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

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