

Patient Labeling

What is the device?

The hip system is the Ceramic TRANSCEND® Articulation System and is composed of the following parts: the TRANSCEND® Ceramic Liner, the SLT Ceramic Femoral Head and a commercially available, compatible Wright Medical Technology, Inc. hip stem and acetabular shell. Your hip replacement with ceramic parts includes a ceramic socket, a ceramic ball, and a shell, which fits the liner.

Insert line drawings here

Acetabular Shell Acetabular Liner Femoral Head

What is the purpose of the device?

The Ceramic TRANSCEND® Articulation Hip System is indicated for use in total hip joint replacement for reduction or relief of pain and/or improved hip function in skeletally mature patients with non-inflammatory degenerative joint disease such as Osteoarthritis, Avascular Necrosis, Congenital Hip Dysplasia, and Traumatic Arthritis. These diagnoses are defined below:

Osteo/degenerative Arthritis – the breakdown of cartilage (rubbery type of tissue that pads the joints) in your joints, which causes your hip bones to rub painfully together.

Traumatic Arthritis –inflammation (swelling, redness, and pain in tissues caused by injury or damage) of a joint resulting from an injury and characterized by breakdown of the bone and rubbery tissue, bleeding in the joint space, and increased thickness of the bone, a flattening of the joint surface, joint rubbery tissue separation from the underlying bone and erosion of the bone.

Congenital Hip Dysplasia – dislocation of the hip at the time of birth due to abnormal development of one or all of the components of the hip joint: the acetabulum (the cup shaped socket in the hip bone); the femoral head; and the surrounding joint capsule and soft tissues.

Avascular Necrosis – a loss of blood supply to the hip bones characterized by changed contour (shape) and increased density (thickness) of the bone, a flattening of the joint surface.

What happens during the implant procedure?

The surgical procedure for a total hip is where your diseased hip bone is removed and replaced with a ball on a stem (SLT Ceramic Femoral Head and SLT taper). The stem is inserted into the thighbone. After a special instrument makes the right size and shape, the liner and shell are placed there and held in place by screws. The ball is then placed into its new socket.

When should the device not be used (Contraindications)?

Absolute contraindications include:

1. obvious infection;
2. distant centers of infections (which may be spread through the blood stream or circulation to the implant site);
3. rapid disease progression as obvious by joint destruction or bone absorption (loss of bone) seen on x-ray photographs;
4. patients whose bones have not stopped growing;
5. cases where muscles may be too weak to work satisfactorily (e.g., prior paralysis [loss of function] and fusion [joining together]), poor bone stock (weak bones), poor skin coverage around hip joint causing the procedure to be unadvised;
6. inflammatory degenerative joint disease (like rheumatoid arthritis);
7. joints with nerve disorders;
8. patients who are obese;
9. nerve or muscle disease that may negatively have an effect on gait (walking) or weight bearing.

This implant has not been tested to see if it is safe or effective to use as a replacement of an existing total hip replacement.

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 use 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 reactions/complications can arise during and after surgery and may require medical intervention (such as surgery) and/or implant removal. The risks and complications include:

1. Advancing bone breakdown and loss may occur around the hip implant parts due to foreign body reaction to particles.
 - Particles of hip implant materials, cement, and bone are generated by contact between hip implant parts and contact between hip implant parts and bone.

- Particles may be caused by bonding (attachment), scraping, and/or breakage.
- Also, particles in between the hip implant parts or between the hip implant parts and bone may cause more particles of implant materials or bone to be formed at an increasing rate.

Osteolysis (dissolving of bone) can lead to future problems such as removing or replacing the hip implant parts.

2. Wear of the alumina ceramic joint surfaces of hip parts has been reported following total hip replacement. Higher rates of wear may be caused by particles of cement, metal, or other debris, which can cause scraping of the joint surfaces. Higher rates of wear may shorten the useful life of the hip, and lead to early revision surgery to replace the worn out hip parts.
3. Although rare, metal allergy reactions in patients following hip surgery have been reported. The presence of any implant material can be seen as foreign and the body tissue may react against it.
4. Nerve damage, without clinical signs or symptoms, has been reported, and may occur as the result of having hip surgery.
5. Dislocation and subluxation (partial dislocation) of hip parts can result from improper positioning of the components. Muscle and rubbery tissue laxity (slackness) can also contribute to these conditions.
6. Hip parts can loosen or migrate (move) due to trauma or improper attachment.
7. Infection can lead to failure of the hip joint.
8. While rare, fatigue fracture (breakage) of the hip parts can occur as a result of trauma, strenuous activity, improper position, or time implanted in the body (service life).

What might increase the risk of failure?

- 1) patients who are unable to follow instructions given by medical professionals;
- 2) noticeable bone loss, severe decreased bone mass (osteoporosis);
- 3) disorders that interfere with the body's ability to absorb nutrients, which may slow bone formation;
- 4) softening of the bones (osteomalacia);
- 5) poor hope for good wound healing (e.g., chronic pressure ulcers, end-stage diabetes, severe protein deficiency and/or malnutrition (not enough food to serve the body's needs) and;
- 6) foreign body sensitivity; when material sensitivity is suspected, appropriate tests should be made prior to material selection or implant procedure.

What are the complications to expect during surgery or shortly after?

- 1) pain;
- 2) femoral or acetabular perforation (hole in hip parts), or broken bones;
- 3) broken bone while seating the device;
- 4) damage to blood vessels;
- 5) temporary or permanent nerve damage resulting in pain or numbness of the affected limb; and
- 6) undesirable shortening or lengthening of the limb caused by improper selection of the implant size;
- 7) traumatic arthrosis (disease of the joint) of the hip from intraoperative positioning of the extremity;
- 8) cardiovascular disorders including blood clots in the veins or lungs, or heart attack;
- 9) pocket of blood caused by bleeding from a broken blood vessel which appears "black and blue";
- 10) delayed wound healing; and
- 11) infection.

What kind of problems could happen later on?

- 1) pain;
- 2) trochanteric avulsion (where a small piece of the thigh bone is pulled away) as a result of excess muscular tension, early weight bearing, or accidental weakening during surgery;
- 3) trochanteric non-union (broken bone that does not heal properly) due to weak reattachment and or early weight bearing;
- 4) problems with either leg because of differences in leg lengths or because of lack of enough muscle;
- 5) broken bone by trauma or excessive loading (weight or force), particularly in the presence of poor bone stock;
- 6) periarticular calcification (calcium deposits around a joint) or ossification (bone formation), with or without obstacles to joint mobility (able to move); and
- 7) inadequate range of motion due to improper selection or positioning of hip parts, by femoral impingement (parts striking each other), and periarticular calcification (calcium deposits around a joint).

What role does the patient have?

There are limits to what you can do after you receive your new hip. You will need to protect your hip implant from full weight bearing until adequate attachment and healing have occurred. After you have adequate attachment and healing, any activity above normal (such as playing basketball or heavy physical work) or unexpected trauma to the hip can cause broken bones, loosening, or wear of the hip implant and its parts. Loosening of the hip parts can result in increased production of wear particles, as well as damage to the bone, making another surgery (revision) more difficult.

Please read and comply with the follow-up care and treatment instructions given to you by your physician.

When should the patient contact the doctor?

- Redness, swelling, or drainage from around your incision,
- An unexplained fever (temperature over 100 degrees Fahrenheit or 38 degrees Centigrade) or chills that last more than a day,
- Severe hip pain that is not relieved by your pain medicine,
- Any unusual shortening or rotation (turning) of your leg, or
- Any sudden swelling in your thigh or calf.

This hip device does not replace normal healthy bone. The hip parts can break or become damaged as a result of strenuous activity, trauma, or even normal use, have a limited expected service life, and may need to be replaced at some time in the future.

What Alternatives does the patient have?

Depending on individual circumstances, alternative procedures may include the use of other commercially available total hip replacement parts already approved or cleared by 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.