

LABELING

Instructions for Use

DEVICE DESCRIPTION

The Ceramic TRANSCEND® Articulation System consists of the following components:

- Ceramic TRANSCEND® Acetabular Liner
- SLT Ceramic Femoral Head

The Ceramic TRANSCEND® Articulation System will be implanted with commercially available Wright Medical Technology (WMT) femoral stems, acetabular shells, apical hole plugs, and self-tapping cancellous bone screws.

Commercially Available Components

The 28 and 32mm SLT ceramic femoral heads, acetabular shells, femoral stems, apical hole plug, and self-tapping cancellous bone screw have been previously cleared by FDA for commercialization via the 510(k) Pre-Market Notification Process.

Ceramic TRANSCEND® Acetabular Liner

The Ceramic TRANSCEND® Acetabular Liner is manufactured high purity, dense aluminum oxide (99.7%) conforming to ISO 6474 and is designed for use with the metal Wright Medical Technology TRANSCEND® acetabular shell. The liners are available in three inside diameters: 28mm, 32mm, and 36mm.

SLT Alumina Ceramic Femoral Head

The SLT Alumina Ceramic Femoral Head is manufactured from high purity, dense aluminum oxide (99.7%) conforming to ISO 6474. It is available in three sizes: 28mm, 32mm, and 36mm and three neck lengths: short, medium, and long.

INDICATIONS:

The Ceramic TRANSCEND® Articulation Hip System is indicated for use in primary total hip arthroplasty in skeletally mature patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and traumatic arthritis.

CONTRAINDICATIONS:

- overt or latent infection in or around the hip joint;
- skeletally immature patients; and
- cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock (tight fixation is critical, bone stock must be adequate), poor skin coverage around hip joint which would create an unjustifiable risk.

WARNINGS:

- Seat the acetabular shell at a 45° inclination with 15° anteversion for proper positioning to decrease the chance for dislocation.
- Always ensure proper alignment and seating of TRANSCEND® Acetabular liner before impacting to prevent chipping or damage.
- Do not reassemble and disassemble the liner component to the acetabular shell because the locking joint and taper joint might become damaged.
- Do not scratch modular shells and tapers to prevent damage to the locking joint.
- Do not use other manufacturer's components with any of the TRANSCEND® components to prevent a mismatch of the tapers. Use only compatible Wright Medical components with the TRANSCEND® components (see product literature for list of appropriate components).
- Replace any component that has been chipped, scratched, or otherwise damaged during the implant procedure.
- Do not implant in obese patients because loading on the ceramic femoral heads may lead to fracture or loss of fixation.
- Implants are for single use only. Do not reuse an implant in order to ensure there has been no damage to the implants.
- Do not re-sterilize components and return all packages with flaws to the manufacturer.

PRECAUTIONS:

- Surgeons must review the training video and materials prior to implanting the Ceramic TRANSCEND® Articulation System.
- Clean surgical debris from the interior of the shell prior to seating the liner into the shell to prevent accelerated bearing wear. Accelerated bearing wear may lead to early failure of the device.
- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.
- Clean and dry surfaces which lock to ensure proper seating and assembly.
- Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load.
- Do not use a metal or zirconia head with the TRANSCEND® Acetabular Liner because this may accelerate bearing wear and lead to early failure of the device.
- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall with screws that are too long can result in internal bleeding and possible damage to vital organs.
- Avoid detachment of porous or HA coatings which could lead to increased debris particles.
- Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular liner.
- Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- In order to prevent sepsis, the physician is advised to follow the following recommendations:
 - Consistent use of prophylactic antibiotics.

- Utilizing a laminar flow clean air system.
- Having all operating room personnel, including observers, properly attired.
- Protecting instruments from airborne contamination.
- Impermeable draping.
- Safety and Effectiveness has not been established in patients with the following conditions:
 - revision hip arthroplasty
 - inflammatory hip joint disease
 - neuropathic hip joint disease

Adverse Events

The adverse events related to total hip replacement surgery reported in the clinical study 959 patients are listed in Table 1.

Event	Clinical Study (n=959)		Whiteside Clinical Study (n=211)	
	Freq.	% of Pop.	Freq.	% of Pop.
Systemic				
Deaths	9	0.9%	0	0%
Pulmonary Embolism	2	0.2%	2	0.9%
Deep Vein Thrombosis	4	0.4%	0	0%
Local	Freq.	% of Pop.	Freq.	% of Pop.
Breakage/Fracture of Component ¹	5	0.5%	2	0.9%
Dislocation (single) of Component ²	8	0.8%	3	1.4%
Dislocation (recurrent) of Component ³	2	0.2%	0	0%
Femoral Fracture	18	1.9%	9	4.3%
Hematoma	2	0.2%	0	0%
Heterotopic Ossification	1	0.1%	1	0.5%
Infection: Deep, Early < 1 year	2	0.2%	0	0%
Infection: Deep, Late > 1 year	1	0.1%	0	0%
Infection: Superficial	7	0.7%	0	0%
Loosening of Component	3	0.3%	2	0.9%
Migration of Component	2	0.2%	0	0%
Persistent Foot Drop	2	0.2%	0	0%
Pain	10	1.0%	0	0%
Perforation of Femur During Reaming	2	0.2%	0	0%
Wear of Component	1	0.1%	0	0%
Subsidence of Component	3	0.3%	2	0.9%
Soft Tissue Trauma	0	0%	0	0%
Wound Problems	2	0.2%	0	0%
Other Local Complication ⁴	10	1.0%	0	0%
Local - Hip	Freq.	% of Pop.	Freq.	% of Pop.
Trochanteric Bursitis	16	1.7%	1	0.5%
Trochanteric Non-union	0	0%	0	0%
Trochanteric Avulsion	4	0.4%	0	0%

Notes:

¹ Clinical Study : Chipping of ceramic acetabular liner during placement requiring intraoperative revision.

Whiteside Clinical Study: Broken metal peg of acetabular cup

² 2 were revised for this reason

³ 1 was revised for this reason.

⁴ Consisted of: 3 cases of irritation/inflammation; 2 cases where patients fell; 1 case of component mismatch; 1 case of liner malposition; 1 case where the acetabular shell seated too deeply in the reamed cavity; 1 case of hip flexor weakness; and 1 case where the anterior abductor pulled off. None of these complications were related to the study hip or the procedure.

Study Design

The study was a prospective, multi-center, historical control, clinical trial. The historical control group was later selected as the population from Whiteside Total Hip System clinical trial consisting of non-inflammatory degenerative joint disease cases. Study patients consisted of individuals over 21 years of age presenting for total hip arthroplasty due to osteoarthritis, congenital hip dysplasia, traumatic arthritis and avascular necrosis. A total of 329 procedures have been performed with the Ceramic TRANSCEND® device in the original pivotal clinical population (Original Clinical Population). An additional 630 devices were implanted under Continued Access. The total number (Original Clinical Population and Continued Access) meeting the inclusion/exclusion criteria as required by the protocol is 959 procedures in 848 patients. Over a two-year period, 211

hip prostheses (179 patients) with metal femoral stems and plastic cups were implanted in the Whiteside Clinical Study.

Clinical Study Patient Assessment

Each patient was evaluated at the immediate and 6, 12, and 24-month post-operative intervals, unless otherwise indicated by complications. At each follow-up visit, a Harris Hip Score and SF-12 was administered as well as obtaining AP and lateral radiographs. Radiographs were reviewed by the implanting surgeon. There were no pre-specified success/failure criteria in the pivotal clinical study.

Demographics

For the study population, there were a total of 965 procedures performed in 854 patients at 12 sites by 19 surgeons. Six of these patients did not meet study inclusion criteria (one procedure enrolled as a replacement for a previously implanted THR and five procedures performed in patients with rheumatoid arthritis). These six procedures are excluded from this analysis. Therefore, the primary analysis sample included 959 procedures for first hip replacements performed in 848 patients.

The patient accounting and Baseline Demographics are summarized in Tables 2 and 3. Note that there were 7 deaths, none of which were related to the study or to the device.

Table 2: Patient Accounting

Evaluation Interval	Original Clinical Patient Population (n=329)			Continued Access Population (n=630)		
	TFU	EFU	AFU (%)	TFU	EFU	AFU (%)
Pre-Op	329	329	100% (n=329)	630	630	100% (n=630)
6 months	329	323	93% (n=300)	602	602	71% (n=430)
12 months	329	321	91% (n=293)	443	442	53% (n=233)
24 months	329	321	94% (n=302)	151	150	0% (n=0)

TFU = Theoretical Follow-Up; EFU = Expected Follow-Up (Theoretical Follow-Up minus deaths and removals without replacement); AFU = Actual Follow-up

Table 3: Baseline and Demographics

Values	Total Study Procedures (n=959)	Whiteside Clinical Study (n=211)
Mean Age in years	51.4 years (range 20-80)	62.7 years (range 22-87)
Gender	595 (62%) Males 364 (38%) Females	112 (53%) Males 99 (47%) Females
Mean Body Mass Index (kg/m ²)	28.8 (range 17.7-65.8)	27.1 (range 22.8-40.9)
Diagnosis		
Osteoarthritis	692 (72.2%)	180 (85.3%)
Avascular Necrosis	189 (19.7%)	31 (14.7%)
Traumatic Arthritis	36 (3.8%)	0
Congenital Hip Dysplasia	42 (4.4%)	0
Mean Baseline Total HHS (range 1-100)	45.1 (range 8.3-95.9)	42.7 (range 11-79)
Mean Baseline Pain HHS (range 0-44)	12.9 (range 0-44)	13.2 (range 0-30)
Mean Baseline Harris ROM° (range 0-5)	3.8 (range -3.1-4.88)	4.1 (range not available)

Efficacy results

Table 4: Efficacy Results - HHS

Primary Efficacy Assessment	Original Patient Population (n=329) ¹	Continued Access Population (n=630) ²	Whiteside Clinical Study (n=211)
Preoperative mean HHS (range)	44.8 (13-89)	45.2 (8-96)	42.7 (11-79)
2 year postop mean HHS (range)	94.8 (34-100)	88.1 (17-100)	92.7 (39-100)
% Excellent/Good Results (HHS 80-100 points) at 2 years postop	92.2%	76.9%	88.2%

Notes:

¹ Original clinical study population includes the first 329 procedures enrolled in the pivotal clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4)

² The *Continued Access* sample (N=630) includes procedures performed after the original clinical population without Month 24+ outcomes. Therefore, outcomes reported were defined on the basis of Last Observation Carried Forward (LOCF) and represent the latest clinical results available for that procedure

Any Radiographic Lucency

Radiolucencies were recorded at each follow-up visit based on if they involved the entire Gruen zone (7 AP femoral zones, 7 lateral femoral zones, 3 AP acetabular zones, and 3 lateral acetabular zones). Table 5 summarizes these results.

Table 5: Any Radiolucency

Lucency	Original Study Population (n=329)	Whiteside Clinical Study (n=211)
Femoral	18 (5.5%)	66 (31.3%)
Acetabular	9 (2.8%)	56 (26.5%)
Overall	22 (6.8%)	77 (36.5%)

In addition, any subsidence was reported for the original study population for 0.9% of the femoral stems and 0.3% of the acetabular cups. In the Whiteside Clinical Study there were two instances of femoral stem subsidence (1.0%).

Implant Survivorship

Implant survivorship was the pre-specified primary endpoint in the pivotal clinical study of the Ceramic TRANSCEND[®] hip. Kaplan-Meier cumulative survivorship is shown in Tables 7 and 8 for the Ceramic TRANSCEND[®] and the Whiteside hips over time.

The cumulative Kaplan-Meier survivorship values for the femoral or acetabular component are shown in tables 6 and 7 based on the longest duration of follow-up available in each study cohort.

Table 6: Ceramic TRANSCEND[®] Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	528	69	8	0.9909	0.0041
24 months	279	78	1	0.9876	0.0066
36 months	1	0	0	0.9308	0.0562

Table 7: Whiteside Clinical Study Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	234	8	3	0.9870	0.0074
24 months	223	70	1	0.9817	0.0090
36 months	152	103	1	0.9719	0.0131
48 months	48	34	3	0.8779	0.0481
60 months	11	11	0	0.8779	0.0481

Revisions and Removals

Eleven devices out of the 959 primary patients enrolled in the trial have been revised or removed. Table 9 summarizes the clinical information pertaining to these cases.

Patient Success Criteria

Table 8 describes the proportion of patients meeting individual clinical success criteria at 2 years postoperatively.

Table 8: Patient Success Criteria at 2 Years

Patient Success Criteria	Original Patient Population (n=329) ¹	Whiteside Clinical Study (n=211)
Absence of Revision (%)	96.7% (n=318)	98.1% (n=207)
Total HHS \geq 70	96.8% (n=318)	95.3% (n=201)
No Complete	99.7% (n=328)	88.5% (n=184)

Notes:

¹ The *Original Patient Population* sample includes procedures in the *Complete Endpoint* (N=309) sample plus procedures with revisions, replacements, or removals prior to Month 24 (N=9); who died prior to Month 24 (N=7); or who had only a partial Harris Hip Score assessment at Month 24 or later (N=4). This sample was constructed in order to facilitate an analysis of efficacy and safety endpoints for hips that were at-risk for a complication and that 'completed the study'. For *Complete Follow-up* procedures (N=329), the Month 24+ endpoint was defined as the Month 24 value and if not available, values after Month 24 were used. Original pivotal clinical population includes the first 329 procedures enrolled in the clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4)

² Absence of complete radiolucency were determined by radiographic evaluation for four views: acetabular AP view (3 regions), acetabular lateral view (3 regions), femoral stem AP view (7 regions), and femoral stem lateral view (7 regions). Complete radiolucency in a view was defined to be present if there was any radiolucency present in all zones comprising that view. Absence of complete radiolucency was defined to be present if none of these four views had complete radiolucency.

Table 9: Summary of Revisions and Removals

Procedures	Age/ Gender	Diagnosis	Duration of Implantation	Reason for Revision/Removal
Revision of acetabular component with bone graft and cage implantation	50/F	AVN	84 days	Migration of acetabular component
Revision of femoral head with a longer neck	29/F	Congenital Hip Dysplasia	1 day	Dislocation
Replaced acetabular component to larger size (32mm) and replaced femoral head to 35mm	43/M	Severe osteoarthritis with mild hip dysplasia	1 day	Dislocation
Replacement of acetabular component, liner, and femoral head. Repair of abductor mechanism.	62/M	Osteoarthritis	38 days	Persistent dislocation following closed reduction; trochanteric fracture with avulsion of abductors
Revision followed by removal and girdlestone procedure	51/M	Traumatic arthritis	210 days	Deep infection and stitch abscess
Replacement of acetabular liner	36/F	Congenital hip dysplasia	3 days	Acetabular liner disassociated from shell
Replacement of acetabular liner and femoral head	41/M	Osteoarthritis	14 days	Increasing pain, suspected infection
Replacement of acetabular liner and femoral head	58/M	Avascular Necrosis	953 days	Excessive wear due to impingement on acetabular cup rim
Replacement of femoral head from 32mm to 28mm	50/M	Osteoarthritis	1 day	Liner/head size mismatch noted on postoperative film
Replacement of (uncemented) femoral stem to cemented stem	56/M	Osteoarthritis	657 days	Pain and progressive subsidence due to undersized (uncemented) femoral stem
Replacement of femoral stem and head	56/F	Osteoarthritis	786 days	Femoral component loosening

INFORMATION FOR PRESCRIBERS

In using total joint prostheses, the surgeon should be aware of the following:

- A. **The correct selection of the prosthesis is extremely important.** The potential for success in total joint replacement is increased by selection of the proper size, shape, and design of the prosthesis. Total joint prostheses require careful seating and adequate bone support. Smaller sized implants are intended for patients of slight weight and a low activity level. Such components could be inappropriate for other patients. Surgeons are encouraged to use their best medical judgement when choosing the proper implant size regardless of the endosteal area of the bone.
- B. **In selecting patients for total joint replacements, the following factors can be critical to the eventual success of the procedure.**
1. **Patient's weight.** An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned and a small size prosthesis must be used.
 2. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
 3. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
 4. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be conducted prior to material selection or implantation.

DEVICE RETRIEVAL EFFORTS

Should it become necessary to remove any or all of the Ceramic TRANSCEND® components, please call Wright Medical Technology at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

HOW SUPPLIED

1. STERILIZATION

This product is supplied sterile and it should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using accepted sterile technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product. This is particularly important in handling porous coated prostheses. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials.

This product is for single use only. Prosthesis should never be reused. While it may appear undamaged, microscopic imperfections may exist which would reduce the service life of the prosthesis.

Prosthesis should never be resterilized or reused after contact with body tissues or fluids, but rather should be discarded.

Warning: Do not resterilize ceramic acetabular liner.

Warning: Do not resterilize ceramic femoral heads.

Warning: Do not resterilize acetabular shells with a liner seated in the shell.

2. COMPONENTS AVAILABLE

Femoral head, acetabular liner, acetabular shell, and bone screws (optional).

CONFORMANCE TO STANDARDS

The materials used in the fabrication of the following device components are in accordance with ASTM material specifications as cited below:

ISO 6474: Implant for surgery – Ceramic Materials Based on Alumina

The material used for the TRANSCEND® Liners and Heads to be marketed conforms in all respects with the current requirements of ISO Standard Specifications for Implant for surgery – Ceramic Materials Based on Alumina (ISO Designation: ISO 6474)

ISO 10993-7: 1995, Biological Evaluation of Medical Devices- Part 7: Ethylene oxide sterilization residuals

The Ceramic TRANSCEND® Articulation System to be marketed conforms to the allowable limits for residual ethylene oxide (EtO) in individual EtO-sterilized medical devices as specified in ISO 10993-7: 1995, Biological Evaluation of Medical Devices-Part 7: Ethylene oxide sterilization residuals.

CAUTION: Federal Law (U.S.) restricts this device to the sale by or on the order of a physician.

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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

		Femoral
	Acetabular	Head
Acetabular	Liner	
Shell		

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 hipbones 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?

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Amendment to P010001

- 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.

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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.