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CONSERVE® Plus Total Resurfacing Hip System

123483-4

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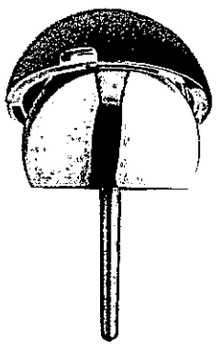
CONSERVE® PLUS TOTAL RESURFACING HIP SYSTEM
(123483-4)

DEVICE DESCRIPTION

The CONSERVE® Plus Total Resurfacing Hip System is a metal-on-metal hip resurfacing system. The system is composed of a stemmed resurfacing femoral component for cemented fixation; and a one-piece acetabular shell for cementless, press-fit fixation. The device is a "resurfacing" hip system because only the surface of the femoral head is removed to implant the femoral component.



The design features of the CONSERVE® Plus Resurfacing Femoral Component are as follows:

- Manufactured from Cast Cobalt Chrome Alloy conforming to ASTM F75.
- Offered in a range of outer diameters from 36mm to 54mm in 2mm increments.
- The articulating surface of the implants is superfinished to insure form tolerance and a fine surface finish.
- The undersurface of the femoral component has a "glass-bead" blasted surface finish (125 Ra Max) and contains a shallow circumferential undercut band at the head's equator.
- A tapered stem geometry.

The design features of the CONSERVE® Plus Acetabular Shells are summarized below:

- Manufactured from Cast Cobalt Chrome Alloy conforming to ASTM F75.
- Porous coated with Cobalt Chrome Alloy sintered beads conforming to ASTM F1377.
- The articulating surface of the implants is superfinished to insure form tolerance and a fine surface finish.
- Available Sizes range from 36mm ID/46mm OD to 54mm ID/64mm OD, in 2mm increments.

Sizing and System Compatibility

The correct selection of the prosthesis is extremely important. The potential for success in total hip resurfacing arthroplasty is increased by selection of the proper size of the prosthesis. Total hip resurfacing prostheses require careful seating and adequate bone support.

The femoral heads are compatible with the following acetabular components.

CONSERVE® Plus Total Resurfacing Hip System Sizing and System Compatibility	
Femoral Component (Nominal Outer Diameter)	**Acetabular Component** (Nominal Inner Diameter/ Nominal Outer Diameter of shell)
36mm	36mm ID/ 46mm OD
38mm	38mm ID/ 48mm OD
40mm	40mm ID/ 50mm OD
42mm	42mm ID/ 52mm OD
44mm	44mm ID/ 54mm OD
46mm	46mm ID/ 56mm OD
48mm	48mm ID/ 58mm OD
50mm	50mm ID/ 60mm OD
52mm	52mm ID/ 62mm OD
54mm	54mm ID/ 64mm OD

INDICATIONS

The CONSERVE® Plus Total Resurfacing Hip System is a single use device intended for hybrid fixation utilizing: cemented femoral head component and cementless acetabular component. The CONSERVE® Plus Total Resurfacing Hip System is intended for use in resurfacing hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally- mature patients having the following conditions:

- Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia/developmental dislocation of the hip (DDH), or
- Inflammatory arthritis such as rheumatoid arthritis.

The CONSERVE® Plus Total Resurfacing Hip System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision.

CONTRAINDICATIONS

- Patients with active or suspected infection in or around the hip joint.
- Patients who are skeletally immature.
- Patients with bone stock inadequate to support the device including:
  - Patients with severe osteopenia should not receive the CONSERVE® Plus Total Resurfacing Hip procedure. Patients with a family history of severe osteoporosis or severe osteopenia;
  - Patients with osteonecrosis or avascular necrosis (AVN) with >50% involvement of the femoral head (regardless of FICAT Grade) should not receive a CONSERVE® Plus Total Resurfacing Hip System device; or
  - Patients with multiple cysts of the femoral head (>1cm) should not receive a CONSERVE® Plus Total Resurfacing Hip System device.

NOTE: In cases of questionable bone stock, a Dual-Energy X-ray Absorptiometry (DEXA) scan may be

necessary to assess inadequate bone stock.

- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery.
- Females of child-bearing age due to unknown effects of metal ion release on the fetus.
- Patients with known moderate to severe renal insufficiency.
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids.
- Patients who are obese and/or with a BMI>35.
- Patients with known or suspected metal sensitivity (e.g., jewelry).

WARNINGS AND PRECAUTIONS:

Only physicians who have received appropriate training and are familiar with the implant components, instruments, procedure, clinical applications, adverse events, and risks associated with the CONSERVE® Plus Total Resurfacing Hip System should use this device. Contact Wright Medical Technology for the surgical technique manual and procedural training protocol.

The CONSERVE® Plus Total Resurfacing Hip System has not been evaluated for safety and compatibility in the MR environment. The CONSERVE® Plus Total Resurfacing Hip System has not been tested for heating or migration in the MR environment.

If the CONSERVE® Plus Total Resurfacing Hip System resurfacing head must be revised to a total hip arthroplasty, Wright does have a commercially available modular CONSERVE® Total Hip System femoral head and stem, for use with the CONSERVE® Plus resurfacing shell.

Risk factors based on clinical study data include patients who have one or more of the following:

- Patients who are female gender;
- Patients requiring a small femoral component (≤ 44mm);
- Patients within the first 60 procedures of a surgeon's cases;
- Patients diagnosed with avascular necrosis, traumatic arthritis, congenital hip dysplasia, rheumatoid arthritis;
- Patients with any previous treatment to the hip;
- Patients with multiple femoral cysts;
- Patients with an acetabular component position of < 30°; and
- Patients with any other joint involvement.

Risk factors based on retrieval analysis include patients who have one or more of the following:

- Patients diagnosed with traumatic arthritis, congenital hip dysplasia, avascular necrosis;
- Patients with large (>1cm) and/or multiple femoral cysts;
- Patients with poor bone quality such as loss of femoral head bone;
- Patients with DEXA scan showing severe osteopenia;
- Patients with femoral neck notching during implantation;
- Impacting femoral component beyond surgical technique recommendations;
- Failing to suction excess blood or bone debris before femoral component implantation;
- Too few or too many drilled holes in top of femoral head along with chamfer holes;
- Incomplete removal of cystic debris in femoral head;
- Removal of anterior osteophyte;
- Too much bone removal either on the acetabular or femoral side;
- Loss of acetabular press-fit either during initial operation or post-operatively;
- Improper distribution of cement;
- Leaving the femoral component proud on the femoral head; and

- Malpositioning of the acetabular component (<30° or >60°).

Risk factors based on use of metal-on-metal hip bearings include:

- Patients on medications (such as high-dose or chronic aminoglycoside treatment).
- Patients with co-morbidities (such as diabetes) that increase the risk of future, significant renal impairment should be advised of the possibility of increase in systemic metal ion concentration. Preoperative and postoperative monitoring of renal function (such as creatinine, GFR, BUN) will be necessary.

The more risk factors a patient has, the greater the risk of procedure failure, thus requiring a revision to the hip. Please refer to Table 9 for revision rates associated with each risk factor based on clinical study data.

Preoperative

- Do not use any component of the CONSERVE® Plus Total Resurfacing Hip System with another manufacturer's implant components, because designs and tolerances may be incompatible and can lead to device failure.
- Radiographic templates are available to assist in the preoperative prediction of component size.
- If, during preoperative planning, an appropriately sized component is not available, the procedure should not take place. An appropriate range of implant sizes should be available prior to performing the surgical procedure.
- Examine instruments for wear or damage before use. While rare, intra-operative instrument breakage can occur. Instruments that have experienced excessive use or force may be susceptible to breakage.

Intraoperative

- Using instruments other than those associated with the CONSERVE® Plus Total Resurfacing Hip System may result in inaccurate placement.
- Use the recommended trial components and templates for size determination, trial reduction and range of motion evaluation; thus preserving the integrity of the actual implants and their sterile packaging.
- The trial prostheses should not be implanted.
- Implants should be accepted by the hospital or surgeon only if received with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Wright Medical Technology, Inc.
- Do not scratch acetabular shells and femoral components to prevent damage to the articulation surfaces. Replace any component that has been scratched or otherwise damaged during the implant procedure.
- Implants are for single use only. Do not reuse an implant . This will ensure there has been no damage to the implants.
- Improper selection, placement, positioning, and fixation of the acetabular shell or femoral component may lead to an increased risk of dislocation, impingement, or femoral neck fracture.
- Always ensure proper alignment and seating of the acetabular and femoral components.
- Malalignment of the components and/or soft tissue imbalance may cause excessive wear and early implant failure.
- Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular shell.
- Avoid notching the femoral neck, as this may lead to femoral neck fracture.
- Avoid placing the femoral component in varus, as varus placement of the femoral component has been associated with femoral neck fracture.
- Avoid excessive impaction force when seating the femoral head, as this may lead to weakening of the femoral neck and subsequent fracture.

- Avoid overly abducting the acetabular component. This can accelerate wear.
- Care should be taken to remove bone chips, bone cement fragments, and metallic debris from the implant site to reduce the risk of debris induced accelerated wear of the articular surfaces of the implant.
- Extra care should be taken to avoid damage to the soft tissue and blood supply during dissection of the capsular tissue.
- Care should be taken to ensure that the Steinman Pin is drilled in to avoid bending during insertion. It is also important to place the Steinman Pin in a neutral or slightly valgus position as a varus placement could lead to a fracture of the femoral neck.
- Extra care should be taken to avoid damage to the soft tissue and blood supply during osteophyte removal.
- Malpositioning of the acetabular shell may increase the risk of dislocation and/or impingement.
- High speed and low torque should be used by setting the power driver to "drill" rather than "ream". Considerable torque can be generated by the sclerotic and normal bone in the femoral head.
- Ensure that all reamed bone is covered by the femoral component.
- Ensure that the femoral component is fully seated.
- Due to the presence of femoral head cysts where large amounts of acrylic are used to fill the defects, irrigation of the femoral component during the curing phase may reduce the potential for thermal necrosis.

Postoperative

- Excessive physical activity levels, patients who have a BMI>35, and trauma to the joint replacement may cause early failure of the implant.
- Loosening of the component may increase production of wear particles and accelerate damage to the bone making successful revision surgery more difficult.
- Routine postoperative follow-up is recommended to monitor implant position and patient well-being over time.

Patient Education

- Warn the patient of the surgical risks, possible adverse effects, and possible operative complications that may occur with joint arthroplasty.
- Warn the patient of the limitations of artificial joint replacement devices.
- Caution the patient to protect the joint replacement from unreasonable stresses and to follow the treating physician's instructions. In particular, warn the patient to strictly avoid high impact activities, such as running and jumping, during the first post-operative year while the bone is healing.
- Warn the patient that artificial joint replacement devices can wear out over time and may require replacement.
- Patients must be instructed in the limitations of the prosthesis including, but not limited to, the impact of excessive loading through patient weight or activity, and must be taught to govern their activities accordingly. 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 surgeon should advise the patient against having unrealistic functional expectations.

POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Reported Device Related Adverse Effects

The most commonly reported adverse events related to the CONSERVE® Plus Total Resurfacing Hip System are:

- femoral neck fracture,
- component migration/loosening,
- femoral subsidence,
- dislocation,
- infection,
- impingement, and
- trochanteric fracture.

A complete list of the frequency and rate of complications and adverse events identified in the clinical study are provided in Tables 13 – 19 of the Summary of Clinical Study section.

Potential Adverse Effects

The following adverse effects may occur in association with hip replacement surgery, including the CONSERVE® Plus Total Resurfacing Hip System:

- Device failure because the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Surgical complications including, but not limited to, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Sudden, pronounced, intraoperative blood pressure decrease due to the use of bone cement.
- Hematoma or damage to blood vessels resulting in large blood loss.
- Delayed wound healing.
- Superficial or deep infection. Infections may occur months to years after surgery. These infections are difficult to treat and may require reoperation with removal surgery and replacement at a later time.
- Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.
- Metal sensitivity reactions, allergic reactions, or metallosis.
- Dislocation and subluxation leading to postoperative joint instability (which may be caused by malpositioning of the implants or muscle / fibrous tissue laxity).
- Loosening of hip resurfacing components can occur. Early mechanical loosening may result from inadequate initial fixation, malalignment, latent infection, premature loading of the prosthesis, or trauma. Late loosening may result from trauma, infection, biological complications (including osteolysis), or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Limb length discrepancy.
- Device related noise such as, clicking, popping, squeaking or grinding.
- Increased hip pain and/or reduced hip function.
- Fatigue fracture of the implants as a result of excessive loading, malalignment, or trauma.
- Osteolysis and/or other peri-prosthetic bone loss.
- Bone perforation or fracture (occurring either intra-operatively or occurring post-operatively as a result of trauma, excessive loading, osteolysis or osteoporosis).
- Periarticular calcification or ossification.
- Wear and deformation of the articular surface (as a result of excessive loading or implant malalignment).
- Pseudotumor.
- Aseptic Lymphocyte Dominated Vasculitis Associated Lesion (ALVAL).

Any of these adverse effects may require medical or surgical intervention. In rare cases, these adverse effects may lead to death. The potential long-term biological effects of metal wear debris and metal ion production are not known.

SUMMARY OF CLINICAL STUDY

Purpose of the Investigation

The purpose of this investigation was to test the hypothesis that the CONSERVE® Plus Total Resurfacing Hip System is as safe and effective as conventional total hip arthroplasty. The CONSERVE® Plus Total Resurfacing Hip System (CONSERVE® Plus) was the investigational treatment and the TRANSCEND® Ceramic Total Hip Arthroplasty System (TRANSCEND® Ceramic) and the TRANSCEND® Metal Total Hip Arthroplasty System (TRANSCEND® Metal) served as the control groups. Safety was determined by collection of the incidence of peri-operative and post-operative complications, revisions, and device related adverse events. Effectiveness was measured via a Composite Clinical Success endpoint that included an evaluation of pain and function using the Harris Hip Score (HHS), patient self-evaluation of health related quality of life which included physical and metal-health components (SF-12), radiographic data, and survivorship as described below.

Study Design

A prospective, multi-center, historically controlled Investigational Device Exemption (IDE) study was conducted using components of the CONSERVE® Plus in the United States. *A priori* objectives were used to demonstrate non-inferiority to the historical control groups in terms of a Month 24+ composite clinical success (CCS) criterion. The historical control groups were derived from the regulatory studies for the TRANSCEND® Ceramic IDE and the TRANSCEND® Metal IDE.

The following table (Table 1) provides a comparison of the investigational and control group study parameters.

Table 1: Comparisons of Investigational and Control Group Study Parameters

Protocol Element	CONSERVE® Plus	Ceramic TRANSCEND	Metal TRANSCEND
Type of Study	IDE Hip Resurfacing	IDE Total Hip Arthroplasty	IDE Total Hip Arthroplasty
Bearing Type	Metal on Metal	Ceramic on Ceramic	Metal on Metal
Study Design	Prospective, non-randomized, historical control	Prospective, non-randomized, historical control	Prospective, non-randomized, historical control
Number of Centers	11	10	19
Dates of First Enrollment	29-Aug-00	7-Apr-97	15-Sep-97
Dates of Last Enrollment	25-May-06	12-Jun-01	23-Jul-01
Number of Procedures	1366 All Enrolled- Audited 292 Pivotal Unilateral Efficacy Cohort (Original Shell) 680 All Enrolled Unilateral (Original Shell) Cohort 203 Bilateral Cohort (Original Shell)	963 All Enrolled 341 Pivotal Unilateral Efficacy Cohort 668 Complete Follow-up Safety Cohort 255 Bilateral Cohort	388 All Enrolled 322 Pivotal Unilateral Efficacy Cohort 345 Complete Follow-up Safety Cohort 64 Bilateral Cohort
Follow-up Intervals	Preoperative Operative 6 month 12 month 24 month 24+ Month	Preoperative Operative 6 month 12 month 24 month 24+ Month	Preoperative Operative 6 month 12 month 24 month 24+ Month
Outcome Measures	Harris Hip Score SF-12 Radiographic Evaluation Adverse Event Reporting	Harris Hip Score SF-12 Radiographic Evaluation Adverse Event Reporting	Harris Hip Score SF-12 Radiographic Evaluation Adverse Event Reporting

Note: For the purpose of including available data beyond the Month 24 window, a 24+ Month interval was created. The 24+ month evaluations include 24 month evaluations completed, as well as data from a later visit, if the 24 month evaluation was not available.

Study Inclusion and Exclusion Criteria

Table 2 lists the inclusion/exclusion criteria of the studies in which clinical data was collected for Groups I (CONSERVE® Plus), C1 (TRANSCEND® Ceramic) and C2 (TRANSCEND® Metal). If a criterion in Group I was identical to criteria in Groups C1 and/or C2, "identical criterion" is indicated. Where a criterion in a Group was not included in one or more of the other Groups "criterion not specified in protocol" is stated.

Table 2: Inclusion / Exclusion Criteria for Studies on Groups I, C1 and C2

INCLUSION CRITERIA		
Group I	**Group C1**	**Group C2**
Primary hip surgery for Noninflammatory Degenerative Joint Disease (NIDJD) such as osteo/degenerative arthritis, traumatic arthritis, congenital hip dysplasia, and avascular necrosis.	Identical Criterion	Identical Criterion
Primary hip surgery for Inflammatory Degenerative Joint Disease (Rheumatoid arthritis)	Criterion not specified in protocol	Criterion not specified in protocol
Skeletally mature or at least 18 years of age.	Skeletally mature and 21 years of age or older.	Identical Criterion
Signs the Informed Consent form.	Identical Criterion	Identical Criterion
Already enrolled in the study and present with a need for revision of either or both resurfacing components. These patients may have the failed component(s) revised with an investigational(s) component.	Already enrolled into the study and present with a need for revision may have the failed component revised with an investigational component as long as all components including the shell and femoral stem are revised. Revision of ceramic components only is not allowed.	Already enrolled into the study and present with a need for revision of the metal liner/acetabular shell component or present with a need for revision of the metal head/femoral stem component may have the failed component revised with an investigational component.

EXCLUSION CRITERIA		
Group I	**Group C1**	**Group C2**
Previous fusion, acute femoral neck fracture and/or above knee amputation.	Criterion not specified in protocol	Criterion not specified in protocol
Active infection.	Identical Criterion	Identical Criterion
Pregnant.	Pregnant or whose pregnancy status is unknown.	Pregnant or whose pregnancy status is unknown.
Neurologic or musculoskeletal disease that may adversely affect gait or weight-bearing.	Identical Criterion	Identical Criterion
Previously undergone an ipsilateral hemi resurfacing, total resurfacing, total bipolar, unipolar or total hip replacement device.	Previously undergone a total bipolar or unipolar hip replacement device.	Previously undergone a total bipolar or unipolar hip replacement device.
Active hepatitis or HIV infection.	Identical Criterion	Identical Criterion
Prisoners.	Identical Criterion	Identical Criterion
Body Mass Index (BMI) of >35.	Three times normal body weight.	Three times normal body weight.
Neuropathic joints.	Identical Criterion	Identical Criterion
Severe documented psychiatric disease.	Criterion not specified in protocol	Severe documented psychiatric disease.
Require structural bone grafts.	Criterion not specified in protocol	Criterion not specified in protocol
Documented allergy to cobalt chromium molybdenum.	Criterion not specified in protocol	Criterion not specified in protocol
Ipsilateral girdlestone.	Criterion not specified in protocol	Criterion not specified in protocol
Sickle cell disease or trait	Criterion not specified in protocol	Criterion not specified in protocol
Significant femoral head or neck deformity or significant acetabular wall deficiency.	Criterion not specified in protocol	Criterion not specified in protocol
Criterion not specified in protocol	Criterion not specified in protocol	Diagnosed with osteoporosis.
Criterion not specified in protocol	Criterion not specified in protocol	History of malignancy.

Composite Clinical Success (CCS) Endpoints

A patient was defined as a success at the Month 24+ follow-up timepoint if all of the following CCS criteria were met:

- No worse than 'mild' pain (Harris Hip Score item ≥ 30 points).
- Ability to walk at least '2 to 3 blocks' (Harris Hip Score item ≥ 5 points).
- Ability to climb stairs 'in any manner' (Harris Hip Score item ≥ 1 point).
- Ability to 'enter public transportation' (Harris Hip Score item = yes).
- Comfortable in a high chair for at least one-half hour (Harris Hip Score item ≥ 3 points).
- Putting on shoes and socks 'with ease' (Harris Hip Score item = 4 points).
- An overall Harris Hip Score ≥ 80 points.
- An increase in the Harris Hip Score of at least 15 points relative to baseline.
- A value for the total SF-12 score (sum of physical component score and mental-health component score) at least as large as the pre operative value.
- Absence of complete radiolucency, which was determined by independent radiographic evaluation of four views: acetabular AP view (3 regions), acetabular lateral view (3 regions), femoral stem AP view (3 regions), and femoral stem lateral view (3 regions). Complete radiolucency in a view was defined to be present if there was any radiolucency of any size present in all zones comprising that view.
- Did not undergo revision, removal, or replacement of any component of the device up to that point in time.
- Did not experience a serious, device-related adverse event up to that point in time.

Study Population

Clinical study data was collected on 1851 hips implanted with the CONSERVE® Plus. A subset of the data was audited and these audited 1366 procedures (1206 patients) constitute the All Enrolled Audited cohort. Of these 1366 procedures, 680 were unilateral procedures implanted with the CONSERVE® Plus resurfacing femoral component and the original acetabular shell (described in the Device Description above) and were eligible, based on date of surgery, for the 24+ Month follow-up. There were 458 procedures within the1366 procedure cohort that also received the CONSERVE® Plus resurfacing femoral component but a different version of the acetabular shell which is not included in this labeling. These procedures are included in the 1366 procedure cohort to provide a complete description of device safety.

Table 3 describes the various cohorts assessed in this clinical study.

Table 3: Study Populations

COHORT	SAMPLE SIZES	DEFINITION
All Enrolled Audited	1366 procedures 1206 patients	This cohort has dates of surgery from 8/29/00 to 11/20/06. Data includes procedures implanted with resurfacing femoral component and either the original version of the acetabular shell (described in the Device Description above) or a different version of the acetabular shell which is not included in this labeling. Cohort used to provide supporting evidence of safety. All 1366 procedures were audited by a 3rd party.
Pivotal Unilateral Efficacy Cohort (Original Shell)	292 procedures 292 patients	This cohort has dates of surgery from 10/17/00 to 04/08/02. Includes unilateral non-inflammatory degenerative joint disease (NIDJD) procedures. Staged bilateral patients whose 24 month evaluation occurred prior to having the contralateral hip replacement are also included. Patients enrolled in separate training arm during this time period are not included. All patients in this cohort received the original version of the acetabular shell. Used to evaluate safety and efficacy and the Composite Clinical Success (CCS) definition to determine study success.
All Enrolled Unilateral (Original Shell)	680 procedures 680 patients	This cohort has dates of surgery from 8/28/00 to 01/19/06. This cohort includes all unilateral NIDJD procedures implanted after enrollment was completed for the Pivotal Unilateral Efficacy cohort; all unilateral rheumatoid arthritis procedures; all unilateral training arm procedures; and, were due, based on date of surgery, for Month 24 follow-up or later. All patients in this cohort received the original version of the acetabular shell. This cohort is used to provide supporting evidence of safety.
Bilateral Arm (Original Shell)	203 procedures 118 patients	This cohort has dates of surgery from 11/20/00 to 05/11/06. This cohort includes all patients implanted bilaterally (simultaneously or staged) prior to their Month 24 assessment. All patients in this cohort received the original version of the acetabular shell. This cohort is used to provide supporting evidence of safety.

Note: Due primarily to the fact that the All Enrolled Audited cohort contains 458 procedures implanted with a different version of the acetabular shell which is not included in this labeling, the Pivotal Unilateral Efficacy (Original Shell), All Enrolled Unilteral (Original Shell) and Bilateral Arm (Original Shell) cohorts, described in the above table, do not completely comprise the total 1366 procedures. The composition of the 1366 procedures in the All Enrolled Audited cohort is as follows: 292 Pivotal Unilateral Efficacy procedures, 656 Continued Access procedures, 318 Bilateral procedures, 35 Inflammatory Arm procedures, 8 Training Arm procedures and 57 procedures performed by a site whose data was excluded from the Pivotal Unilateral Efficacy cohort (Original Shell) due to audit findings.

The core data collected from these cohorts was the same. In addition, the follow-up time points and the intervals around these time points were analyzed in the same manner. Identified below are the follow-up time points and the corresponding intervals used within the study which are based on the number of days after the operative procedure (Table 4). For the purpose of including available data beyond the Month 24 window, when the Month 24 data was missing, a 24+ Month interval was created. The 24+ month evaluations include 24 month evaluations completed, as well as data from a later visit, if the 24 month evaluation was not available.

Table 4: Study Intervals

	Actual (B) Extended Interval (Days)	Actual (A) FDA Guidance Interval (Days)
Immediate	1-45	1-56
Month 6	46-210	168-196
Month 12	211-425	305-425
Month 24	426-790	670-790
Month 24 +	Any evaluation 22+ months = 24+	Any evaluation 22+ months = 24+

Baseline Characteristics of Investigational and Control Groups

The summary statistics / comparisons for patient demographics and baseline variables for the Pivotal Unilateral Efficacy (Original Shell), All Enrolled Audited, All Enrolled Unilateral (Original Shell), and Bilateral Arm (Original Shell) cohorts and the two historical controls are displayed in Tables 5 and 6 below.

Significantly different ($p<0.05$) preoperative demographic variables between the CONSERVE® Plus Pivotal Unilateral Efficacy cohort (Original Shell) (Group I) and the TRANSCEND® Ceramic (Group C1) were gender, age, BMI, height in females, and preoperative mean Harris Hip total score. Harris Hip pain score was borderline significant ($p=0.052$). Significantly different ($p<0.05$) preoperative demographic variables between the CONSERVE® Plus Pivotal Unilateral Efficacy cohort (Original Shell) and the TRANSCEND® Metal (Group C2) were gender, age, BMI, weight in males, and preoperative Harris Hip total and pain scores.

Table 5
Demographic Characteristics and Baseline Function in
Pivotal Unilateral Efficacy Cohort (Original Shell) Patients and Unilateral Control Patients

	Pivotal Unilateral Efficacy Cohort (Original Shell) (I)		Ceramic THR Controls (C1)		Metal THR Controls (C2)		I vs. C1[1] p-values	I vs. C2[2] p-values
Number of procedures	292	.	341	.	322	.	.	.
Number of patients	292	.	341	.	322	.	.	.
Gender	n	%	n	%	n	%	0.046	0.046
Males	202	69.2%	210	61.6%	198	61.5%	.	.
Females	90	30.8%	131	38.4%	124	38.5%	.	.
Age	Mean	SD	Mean	SD	Mean	SD	<0.001	<0.001
≥65	13	4.5%	65	19.1%	66	20.5%	.	.
<65	279	95.5%	276	80.9%	256	79.5%	.	.
Males	Mean	SD	Mean	SD	Mean	SD		
Age at surgery (yrs)	48.8	9.6	52.5	11.5	53.3	11.9	<0.001	<0.001
Body Mass Index (kg/m^2)	28.1	4.3	29.6	5.8	30.1	6.0	0.020	0.001
Height (inches)	70.3	3.0	69.7	3.3	70.2	3.3	0.433	0.776
Weight (lbs)	197.8	32.9	204.2	40.2	210.8	42.9	0.171	0.002
Females	Mean	SD	Mean	SD	Mean	SD		
Age at surgery (yrs)	48.9	8.9	53.3	13.0	53.7	11.7	0.006	<0.001
Body Mass Index (kg/m^2)	27.1	6.1	29.3	8.1	29.0	7.3	0.038	0.050
Height (inches)	65.1	2.9	64.2	3.5	64.4	3.1	0.035	0.125
Weight (lbs)	163.1	37.2	171.1	43.2	171.0	43.2	0.251	0.281
Diagnosis	n	%	n	%	n	%	0.157[4]	0.363[4]
Osteo/degenerative arthritis	230	78.8%	243	71.3%	243	75.5%	.	.
Avascular necrosis	34	11.6%	58	17.0%	53	16.5%	.	.
Traumatic arthritis	13	4.5%	21	6.2%	13	4.0%	.	.
Congenital hip dysplasia	15	5.1%	19	5.6%	13	4.0%	.	.
Rheumatoid Arthritis	0	0.0%	0	0.0%	0	0.0%	.	.
Health Related Quality of Life (SF-12)	Mean	SD	Mean	SD	Mean	SD		
SF-12 PCS Z-score[3]	-1.82	1.19	-1.88	1.09	-1.85	1.18	0.991	0.924
SF-12 MCS Z-score[3]	0.00	1.16	0.05	1.18	-0.01	1.10	0.877	0.365
Harris Hip Score	Mean	SD	Mean	SD	Mean	SD		
Harris Hip Total Score	49.4	11.7	45.3	12.8	47.6	14.2	<0.001	0.026
Harris Pain Category[6]	n	%	n	%	n	%	0.052[5]	<0.001[5]
None/Ignores	0	0.0%	1	0.3%	5	1.6%	.	.
Slight	0	0.0%	2	0.6%	10	3.1%	.	.
Mild	5	1.7%	9	2.6%	11	3.4%	.	.
Moderate	105	36.1%	88	25.8%	90	28.0%	.	.
Marked	175	60.1%	229	67.2%	185	57.6%	.	.
Totally disabled	6	2.1%	12	3.5%	20	6.2%	.	.
	n	%	n	%	n	%		
Any Previous Treatment	45	15.4%	58	17.0%	46	14.3%	0.587	0.695
Other Joint Involvement	75	25.7%	70	20.5%	86	26.7%	0.124	0.773
Any bone graft	63	21.6%	85	24.9%	77	23.9%	0.321	0.491

Notes:

[1] I vs. C1 is Pivotal Unilateral Efficacy Cohort (Original Shell) vs. Ceramic THR controls: For interval variables, p-values are from ANOVA pairwise contrasts; for nominal variables, p-values are from pairwise chi-square statistics; for Harris Hip Total, p-values are from pairwise Wilcoxon rank sum tests.

[2] I vs. C2 is Pivotal Unilateral Efficacy Cohort (Original Shell) vs. Metal THR controls: For interval variables, p-values are from ANOVA pairwise contrasts; for nominal variables, p-values are from pairwise chi-square statistics; for Harris Hip Total, p-values are from pairwise Wilcoxon rank sum tests.

[3] SF-12 PCS and MCS Z-scores are age-adjusted and based on US national reference values.

[4] A 2 X 5 Chi square test was performed for Diagnosis versus controls

[5] A 2 X 6 Chi square test was performed for the Harris Hip Score Pain Category versus controls.

[6] One patient was missing complete pain assessment in baseline Harris Hip Score.

Table 6
Baseline and Demographic Characteristics
All Enrolled Unilateral (Original Shell), Bilateral (Original Shell), and All Enrolled Audited Cohorts

	All Enrolled Unilateral (Original Shell) n = 680		Bilateral (Original Shell) n = 203		All Enrolled Audited n = 1366	
	N	**%**	**N**	**%**	**N**	**%**
Number of procedures	680		203		1366	
Number of patients	680		118		1206	
Gender	**N**	**%**	**N**	**%**	**N**	**%**
Males	484	71.2%	153	75.4%	981	71.8%
Females	196	28.8%	50	24.6%	385	28.2%
Age	**n**	**%**	**n**	**%**	**n**	**%**
≥65	42	6.2%	11	5.4%	104	7.6%
<65	638	93.8%	192	94.6%	1262	92.4%
Males	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age at surgery (yrs)	50.1	9.9	49.1	10.0	50.3	9.9
Body Mass Index (kg/m^2)	28.1	4.2	27.4	3.7	28.0	3.9
Height (inches)	70.4	2.7	70.7	3.0	70.6	2.8
Weight (lbs)	198.6	32.9	195.7	32.4	198.3	32.0
Females	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age at surgery (yrs)	48.7	10.1	45.3	8.5	49.6	10.7
Body Mass Index (kg/m^2)	26.2	5.3	27.3	6.5	26.4	5.4
Height (inches)	64.9	2.8	65.6	3.6	65.2	3.0
Weight (lbs)	157.2	33.6	166	37.2	159.8	34.1
Diagnosis	**n**	**%**	**n**	**%**	**n**	**%**
Osteo/degenerative arthritis	519	76.3%	159	78.3%	1054	77.2%
Avascular necrosis	70	10.3%	28	13.8%	138	10.1%
Traumatic arthritis	31	4.6%	0	0.0%	39	2.9%
Congenital hip dysplasia	41	6.0%	16	7.9%	100	7.3%
Rheumatoid Arthritis	19	2.8%	0	0.0%	35	2.6%
Health Related Quality of Life (SF-12)	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
SF-12 PCS Z-score	-1.88	1.16	-2.21	1.22	-1.92	1.16
SF-12 MCS Z-score	0.15	1.10	0.22	1.13	0.20	1.10
Harris Hip Score	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Total Score	50.6	12.0	49.6	12.9	50.7	11.9
Harris Pain Category[1]	**n**	**%**	**n**	**%**	**n**	**%**
None/Ignores	1	0.1%	1	0.5%	2	0.1%
Slight	5	0.7%	1	0.5%	7	0.5%
Mild	12	1.8%	8	4.0%	36	2.6%
Moderate	267	39.4%	70	34.7%	507	37.2%
Marked	377	55.6%	112	55.4%	781	57.3%
Totally disabled	16	2.4%	10	5.0%	29	2.1%
Any Previous Treatment	96	14.1%	10	4.9%	167	12.2%
Other Joint Involvement	172	25.3%	170	83.7%	550	40.3%
Any bone graft	164	24.1%	35	17.2%	281	20.6%

Note:
[1]Two patients were missing pain assessment in baseline Harris Hip Score.

Patient Accounting

The accounting of follow-up evaluations for the CONSERVE® Plus Pivotal Unilateral Efficacy cohort (Original Shell) (Group I) and the control groups (C1 and C2) are provided in Table 7.

Table 7
Procedure Accounting and Follow-up Compliance Table
Pivotal Unilateral Efficacy Cohort (Original Shell) (I), Ceramic THR Unilateral Controls (C1), Metal THR Unilateral Controls (C2)

As of Date of Database Closure	Pre-Op			Post-Op			Month 6			Month 12			Month 24			Month 24+		
	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2
(1) Theoretical follow-up	292	341	322	292	341	322	292	341	322	292	341	322	292	341	322	292	341	322
(2) Cumulative deaths including non-theoretically due	0	0	0	0	0	0	0	0	0	0	1	1	0	3	1	0	3	1
(3) Cumulative revisions including non-theoretically due	0	0	0	7	5	3	7	5	4	7	6	7	13	7	9	19	10	15
(4) Expected due for clinic visit	292	341	322	285	336	319	285	336	318	285	334	314	279	331	312	279	331	312
(5) Expected due+revisions among theoretically due	292	341	322	292	341	322	292	341	322	292	340	321	292	338	321	292	338	321
All Evaluated Accounting (Actual[B]) Among Expected Due Procedures																		
	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2
(6) Numbers of procedures with any clinical data in interval	291	341	322	232	220	237	238	261	294	248	258	229	235	208	208	268	280	276
(7) All Evaluated Visit Compliance (%)	99.7%	100.0%	100.0%	81.4%	65.5%	74.3%	83.5%	77.7%	92.5%	87.0%	77.2%	72.9%	84.2%	62.8%	66.7%	96.1%	84.6%	88.5%
(8) CCS at Mos. 24, 24+ or HHS+SF12+radio.							202	247	227	239	229	212	228	192	189	270	260	249
(9) Actual[B] % Follow-up for CCS or HHS+SF12+radio.							70.9%	73.5%	71.4%	83.9%	68.6%	67.5%	78.1%	56.8%	58.9%	92.5%	76.9%	77.6%
Within Window Accounting (Actual[A]) Among Expected Due																		
	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2
(10) CCS at Mos. 24, 24+ or HHS+SF12+radio							116	87	100	212	201	187	177	157	148	252	202	202
(11) Actual[A] % Follow-up for CCS or HHS+SF12+radio							40.7%	25.9%	31.4%	74.4%	60.2%	59.6%	60.6%	46.4%	46.1%	86.3%	59.8%	62.9%

Notes for Procedure Accounting and Follow-up Accounting Tables

ROM/Deformity Imputations - If post baseline Harris Hip Score evaluations were complete with the exception of ROM and Deformity, then ROM and/or Deformity were defined to be zero. This is a conservative imputation for both the primary CCS and secondary HHS efficacy criteria, since both require HHS to be equal to 80 points or greater and the maximum HHS score for this imputation can be 91, 95 or 96 points instead of 100 points (depending on whether ROM, Deformity or both were missing).

Actual[B] intervals: Immed Post 1-45 days; 6 Mo. 46-210; 1 Yr. 211-425; 2 Yr. 426-790. For the purpose of including available data beyond the Month 24 window, a 24+ Month interval was created. The 24+ month evaluations include 24 month evaluations completed, as well as data from a later visit, if the 24 month evaluation was not available.

Actual[A] intervals: Immed Post 1-56 days; 6 Mo. 168-196; 1 Yr. 305-425; 2 Yr. 670-790. For the purpose of including available data beyond the Month 24 window, a 24+ Month interval was created. The 24+ month evaluations include 24 month evaluations completed, as well as data from a later visit, if the 24 month evaluation was not available.

[1] The theoretical follow-up is the number of implants that would have been examined if all patients returned on the exact anniversary of their respective initial surgery dates.

[2] Cumulative deaths up to and including the current interval. Although the cumulative numbers of deaths are recorded on this row, only deaths among implants that are theoretically due for that interval are subtracted from theoretically due to determine the number expected due.

Notes for Procedure Accounting and Follow-up Accounting Tables
[3] This row records the cumulative number of failures that have taken place according by the exact anniversary of scheduled follow-up visit. Although the cumulative numbers of failures are recorded on this row, only failures among implants that are theoretically due for that interval are subtracted from theoretically due to determine the number expected due.
[4] Expected due for clinic visit is equal to theoretically due minus deaths and revisions among theoretically due . This row serves as denominator for clinical evaluation % followup.
[5] Expected due plus theoretically due revisions is computed by adding expected due to the number of cumulative revisions among theoretical procedures. This row serves as the denominator for composite clinical success (CCS) outcomes.since revisions are known to be CCS failures.
[6] All Evaluated Accounting (Actual^{B}) is based on the evaluations on-file among those expected due without regard to whether assessment was within the assessment window.
[7] All Evaluated Visit Compliance (%) is computed as the number on-file among those expected due divided by the expected number due expressed as a percentage. All evaluated compliance is based on the presence of any clinical data, even if incomplete, and demonstrates that the procedure is actively followed at least up to the specific interval.
[8] CCS at Mos. 24, 24+ or HHS+change in SF12+radiographic, otherwise (Actual^{B}). For Months 24 and 24+, this row indicates the numbers of procedures with all components on-file that are necessary to evaluate composite clinical success with revisions included as CCS failures. For other time points, this row only indicates that Harris Hip Total scores, change from baseline in SF12, and radiographic evaluations are on-file.
[9] Actual^{B} % Follow-up for CCS or HHS+SF12+radio. This is the count of CCS procedures divided by the count of the expected due + revisions among theoretically due.
[10] CCS at Mos. 24, 24+ or HHS+change in SF12+radiographic, otherwise (Actual^{A}). For Months 24 and 24+, this row indicates the numbers of procedures with all components on-file that are necessary to evaluate composite clinical success with revisions included as CCS failures. For other time points, this row only indicates that Harris Hip Total scores, change from baseline in SF12, and radiographic evaluations are on-file.
[11] Actual^{A} % Followup for CCS or HHS+SF12+radio. This is the count of CCS procedures divided by the count of the expected due + revisions among theoretically due.

The following cohort follow-up rates are also of interest:

All Enrolled Audited Cohort

The follow-up rate at Month 24+ for patients with complete information to determine safety was 76.4% (821/1074) for Group I, 60.4% (568/963) for Group C1, and 79.0% (305/386) for Group C2.

All Enrolled Unilateral (Original Shell) Cohort

The follow-up rate at Month 24+ for patients with complete information to determine safety was 81.2% (540/665).

Bilateral arm (Original Shell) Cohort

The follow-up rate at Month 24+ for patients with complete information to determine safety was 83.8% (160/191).

Safety Data

The safety of the CONSERVE® Plus Total Resurfacing Hip System was evaluated in terms of the following analyses:

- Reasons for Revision,
- Risk Factors,
- Survivorship,
- Adverse Events, and
- Metal Ions.

The risk analysis section identifies the factors which were shown to contribute to revision. Survivorship analyses were conducted according to the Kaplan-Meier approach.

Reasons for Revision

There were a total of 66 (8.0%) revisions reported out of 821 procedures in the CONSERVE® Plus Total Resurfacing Hip System All Enrolled Audited cohort, 36 (6.7%) revisions reported out of 540 procedures in the All Enrolled Unilateral (Original Shell) cohort, 19 (7.0%) revisions reported out of 270 in the Primary Unilateral Efficacy cohort (Original Shell), and 11 (6.9%) revisions out of 160 in the Bilateral (Original Shell) cohort at the 24+ Month interval. A summary of the reason for revision, stratified by study cohort, is provided in Table 8 below.

Table 8
All Revisions/Removals Reported By Cohort for the 24+ Month Interval

	All Enrolled Audited (N=1366) (24+ Month N = 821)			All Enrolled Unilateral (Original Shell) (N=680) (24+ Month N = 540)			Pivotal Unilateral Efficacy Cohort (Original Shell) (N=292) (24+ Month N = 270)			Bilateral Cohort (Original Shell) (N=203) (24+ Month N = 160)		
	n/N	%	Mean # Months	n/N	%	Mean # Months	n/N	%	Mean # Months	n/N	%	Mean # Months
Revision	66/821	8.0%	18	36/540	6.7%	19	19/270	7.0%	22	11/160	6.9%	29
Acetabular Loosening	10	1.2%	16	3	0.6%	31	3	1.1%	31	1	0.6%	10
Acetabular Migration	4	0.5%	9	1	0.2%	16	0	0.0%	N/A	0	0.0%	N/A
Acetabular Protrusion	1	0.1%	31	1	0.2%	31	0	0.0%	N/A	0	0.0%	N/A
Acetaular Loosening & Femoral Neck Fracture	1	0.1%	52	0	0.0%	N/A	0	0.0%	N/A	1	0.6%	52
Femoral Loosening	7	0.9%	36	3	0.6%	23	1	0.4%	19	4	2.5%	46
Femoral Neck Fracture	28	3.4%	11	19	3.5%	12	11	4.1%	16	4	2.5%	13
Impingement	2	0.2%	54	2	0.4%	54	1	0.4%	69	0	0.0%	N/A
Infection	8	1.0%	14	4	0.7%	15	2	0.7%	21	1	0.6%	18
Other												
Increase resistance to bearing motion	1	0.1%	0.23	1	0.2%	0.23	0	0.0%	N/A	0	0.0%	N/A
Abductor Rupture	1	0.1%	16	0	0.0%	N/A	1	0.4%	16	0	0.0%	N/A
*Unknown	1	0.1%	31	1	0.2%	31	0	0.0%	N/A	0	0.0%	N/A
Pain	2	0.2%	17	1	0.2%	11	0	0.0%	N/A	0	0.0%	N/A
Total	66	8.0%	18	36	6.7%	19	19	7.0%	22	11	6.9%	29
* bilateral after 2 Years												

It should be noted that not all of the 66 revisions in the CONSERVE® Plus Total Resurfacing Hip System All Enrolled Audited cohort were deemed to be device related. Of the 66 revisions, 57 were deemed device related and 9 were deemed non-device related. Two patients were revised for impingement, 1 for abductor rupture, 1 due to acetabular protrusion, and 4 for infection. All 8 of these revisions were deemed to be non-device related. One patient was revised for unknown reasons and was not evaluable by the Data Safety Monitoring Board (DSMB).

Revision rates for the All Enrolled TRANSCEND® Ceramic and All Enrolled TRANSCEND® Metal controls were 29 (5.11%) out of 568 procedures and 20 (6.56%) out of 305 procedures, respectively, at the 24+ Month interval. Revision rates for the Pivotal Efficacy TRANSCEND® Ceramic and Pivotal Efficacy TRANSCEND® Metal controls were 10 (3.85%) out of 260 procedures and 15 (6.02%) out of 249 procedures, respectively, at the 24+ Month interval.

Device Failure Risk Analysis

Methods

Risk Factor Analyses were performed to identify factors associated with increased risk of device failure. These analyses were performed for the All Enrolled Unilateral (Original Shell) cohort (N=680), the Pivotal Unilateral Efficacy cohort (Original Shell) (N=292) and the Bilateral (Original Shell) (N=203) cohort.

Data for the following variables were collected either as part of the retrieval analysis or clinical study:

Variables assessed via retrieval analysis:
Non-osteoarthritis diagnosis
Avascular Necrosis
Large (>1cm) and/or multiple femoral cysts
Poor bone quality such as loss of femoral head bone
DEXA scan showing severe osteopenia
Absence of collagen disease
Femoral neck notching during implantation
Impacting femoral component beyond surgical technique recommendations
Failing to suction excess blood or bone debris before femoral component implantation
Increased number of drilled holes in top of femoral head along with chamfer holes
Incomplete removal of cystic debris in femoral head
Removal of anterior osteophyte
Too much bone removal either on the acetabular or femoral side
Loss of acetabular press-fit either during initial operation or post-operatively
Improper distribution of cement
Leaving the femoral component proud on the femoral head
Malpositioning of the acetabular component (<30° or >60°)
Variables assessed via clinical data:
Female vs. male gender
A non-osteoarthritis diagnosis (AVN, Traumatic Arthritis, Congenital Hip Dysplasia, Rheumatoid Arthritis)
Pre-surgical Harris Hip Score in the lowest quartile (defined as less than 43.6 points)
Pre-surgical Harris Hip pain category rated as 'marked pain' or worse
Any previous treatment on involved hip (i.e., osteotomy, core decompression, hemi-resurfacing, or internal fixation)
Other joint involvement
Any bone graft used during procedure
Presence of femoral cysts (single vs. none and multiple v. none)
Procedures done within first 60 at a specific site {learning curve effect}
Small femoral component (≤ 44mm)
Femoral neck angle (<135) in relation to the femoral shaft
Femoral component stem angle (<135) in relation to the femoral shaft
Horizontal acetabular component (< 30 degrees)
Vertical acetabular component (>60 degrees)

Key Findings

Analysis of the above variables led to the determination of risk factors. For the retrieval analysis, a variable was deemed a risk factor if findings of at least one specimen suggested failure due to that variable. Of the 66 revised implants from the All Enrolled Audited cohort, 37 were available for retrieval analysis. Variables meeting the definition of risk factor from those analyses included:

- diagnosis of traumatic arthritis, congenital hip dysplasia, or avascular necrosis,
- large (>1cm) and/or multiple femoral cysts,
- poor bone quality such as loss of femoral head bone,
- DEXA scan showing severe osteopenia,
- femoral neck notching during implantation,
- impacting femoral component beyond surgical technique recommendations,
- failing to suction excess blood or bone debris before femoral component implantation,
- too few or too many drilled holes in top of femoral head along with chamfer holes,
- incomplete removal of cystic debris in femoral head,
- removal of anterior osteophyte,
- too much bone removal either on the acetabular or femoral side,
- loss of acetabular press-fit either during initial operation or post-operatively,
- improper distribution of cement,
- leaving the femoral component proud on the femoral head, and
- malpositioning of the acetabular component (<30° or >60°).

Risk factors were also determined based on clinical data collected within the study. Table 9 provides a summary of the risk of revision in the All Enrolled Unilateral (Original Shell) cohort, Pivotal Unilateral Efficacy cohort (Original Shell), and Bilateral (Original Shell) cohort.

Table 9

Risk of Revision in All Enrolled Unilateral (Original Shell), Pivotal Unilateral Efficacy Cohort (Original Shell), and Bilateral (Original Shell) Stratified by All Procedures in Cohort and Only Procedures with At Least 24 Months Follow-up

		All Enrolled Unilateral (Original Shell)	All Enrolled Unilateral (Original Shell) 24+ month follow-up	Pivotal Unilateral Efficacy Cohort[1] (Original Shell)	Pivotal Unilateral Efficacy Cohort (Original Shell) 24+ month follow-up	Bilateral (Original Shell)	Bilateral (Original Shell) 24+ month follow-up
	Revisions	36	36	19	19	11	11
	N	680	540	292	270	203	160
	%	5.3	6.7	6.5	7.0	5.4	6.9
Female gender	Female	7.7% (15/196)	9.0% (15/167)	11.1% (10/90)	11.5% (10/87)	16.0% (8/50)	18.2% (8/44)
	Male	4.3% (21/484)	5.6% (21/373)	4.5% (9/202)	4.9% (9/183)	2.0% (3/153)	2.6% (3/116)
Non osteoarthritis DX	AVN/RA+	8.7% (14/161)	11.1% (14/126)	6.5% (4/62)	7.0% (4/57)	9.1% (4/44)	12.5% (4/32)
	Osteoarthritis	4.2% (22/519)	5.3% (22/414)	6.5% (15/230)	7.0% (15/213)	4.4% (7/159)	5.5% (7/128)
Baseline HHS < 43.6 (1st quartile)[2]	HHS<43.6	4.7% (8/169)	6.1% (8/132)	5.1% (4/78)	5.8% (4/69)	3.3% (2/61)	4.3% (2/47)
	HHS>=43.6	5.4% (27/496)	6.8% (27/400)	7.1% (15/212)	7.5% (15/199)	6.7% (9/135)	8.1% (9/111)
Baseline Pain >=Marked[3]	Marked/Disabled	5.3% (21/393)	6.6% (21/319)	6.1% (11/181)	6.6% (11/167)	3.3% (4/122)	4.3% (4/93)
	Other	5.3% (15/285)	6.8% (15/220)	7.3% (8/110)	7.8% (8/102)	8.8% (7/80)	10.4% (7/67)
Any Previous Treatment	Prev Trt	6.3% (6/96)	7.5% (6/80)	8.9% (4/45)	9.3% (4/43)	20.0% (2/10)	28.6% (2/7)
	none	5.1% (30/584)	6.5% (30/460)	6.1% (15/247)	6.6% (15/227)	4.7% (9/193)	5.9% (9/153)
Other Joint Involvement	Jt Inv	9.3% (16/172)	12.4% (16/129)	9.3% (7/75)	10.1% (7/69)	5.9% (10/170)	7.6% (10/132)
	none	3.9% (20/508)	4.9% (20/411)	5.5% (12/217)	6.0% (12/201)	3.0% (1/33)	3.6% (1/28)
Any Bone Graft	Bone Graft	4.3% (7/164)	5.4% (7/130)	7.9% (5/63)	8.6% (5/58)	2.9% (1/35)	3.3% (1/30)
	none	5.6% (29/516)	7.1% (29/410)	6.1% (14/229)	6.6% (14/212)	6.0% (10/168)	7.7% (10/130)
Femoral Cysts (Multiple vs not multiple)	>1	4.0% (8/199)	4.7% (8/171)	3.4% (3/89)	3.5% (3/85)	12.0% (6/50)	14.3% (6/42)
	0,1	5.8% (28/481)	7.6% (28/369)	7.9% (16/203)	8.6% (16/185)	3.3% (5/153)	4.2% (5/118)
Femoral Cysts (Any vs none)	Any	6.5% (10/153)	8.3% (10/120)	12.2% (9/74)	12.9% (9/70)	1.8% (1/55)	2.2% (1/45)
	None	4.9% (26/527)	6.2% (26/420)	4.6% (10/218)	5.0% (10/200)	6.8% (10/148)	8.7% (10/115)
1st 60 procedures at a specific site	Within 1st 60	8.0% (28/350)	9.1% (28/308)	7.7% (18/234)	8.2% (18/220)	11.0% (10/91)	12.0% (10/83)
	After 1st 60	2.4% (8/330)	3.4% (8/232)	1.7% (1/58)	2.0% (1/50)	0.9% (1/112)	1.3% (1/77)
Small Femoral Component	< 44	9.0% (18/199)	10.5% (18/171)	12.5% (12/96)	13.2% (12/91)	19.5% (8/41)	22.2% (8/36)
	>=44	3.7% (18/481)	4.9% (18/369)	3.6% (7/196)	3.9% (7/179)	1.9% (3/162)	2.4% (3/124)
Femoral Comp. Neck angle<135°[4, 5]	<135°	4.8% (17/354)	5.4% (17/313)	6.3% (12/192)	6.6% (12/181)	5.1% (5/99)	5.7% (5/87)
	>=135°	5.0% (16/318)	7.2% (16/223)	4.2% (4/96)	4.7% (4/86)	5.0% (5/100)	6.9% (5/72)
Stem Neck angle<135°[4,5]	<135°	4.1% (10/246)	4.6% (10/216)	6.1% (7/114)	6.5% (7/108)	4.4% (3/68)	5.1% (3/59)
	>=135°	5.4% (23/426)	7.2% (23/320)	5.2% (9/174)	5.7% (9/159)	5.3% (7/131)	7.0% (7/100)
Too Horizontal Ace. Component (<30° vs not <30°)[4,6]	<30°	12.5% (5/40)	14.7% (5/34)	13.8% (4/29)	14.3% (4/28)	18.8% (3/16)	21.4% (3/14)
	not <30°	4.4% (28/632)	5.6% (28/502)	4.6% (12/259)	5.0% (12/239)	3.8% (7/184)	4.8% (7/145)
Too Vertical Acetabular Component[4,6]	>60°	4.9% (33/672)	6.2% (33/536)	5.6% (16/288)	6.0% (16/267)	5.0% (10/200)	6.3% (10/159)
	not <60°						

Note:

1. There were no Rheumatoid Arthritis patients included in the Pivotal Unilateral Efficacy Cohort (Original Shell).

2. Regarding Baseline HHS < 43.6 (1st Quartile): 15 evaluations in the All Enrolled Unilateral (Original Shell), 8 evaluations in the All Enrolled Unilateral (Original Shell) 24+ Month follow-up, 2 evaluations in the Pivotal Unilateral Efficacy cohort (Original Shell), 2 evaluations in the Pivotal Unilateral Efficacy Cohort 24+ Month follow-up, 8 evaluations in the Bilateral (Original Shell) and 2 evaluations in the Bilateral (Original Shell) 24+ Month follow-up had an incomplete HHS evaluation at Baseline.

3. Regarding Baseline Pain >/= Marked: 2 evaluations in the All Enrolled Unilateral (Original Shell), 1 evaluation in the All Enrolled Unilateral (Original Shell) 24+ Month follow-up, 1 evaluation in the Pivotal Unilateral Efficacy cohort (Original Shell), 1 evaluation in the Pivotal Unilateral Efficacy Cohort 24+ Month follow-up, and 1 evaluation in the Bilateral (Original Shell) had an incomplete Harris Hip Score Pain assessment at Baseline.

4. Regarding Femoral Component Neck Angle, Stem Neck Angle, Too Horizontal Acetabular Component, and Too Vertical Acetabular Component: 8 evaluations in the All Enrolled Unilateral (Original Shell), 4 evaluations in the All Enrolled Unilateral (Original Shell) 24+ Month follow-up, 4 evaluations in the Pivotal Unilateral Efficacy cohort (Original Shell), 3 evaluations in the Pivotal Unilateral Efficacy Cohort 24+ Month follow-up did not have baseline post-operative radiographic evaluation performed.

5. 4 evaluations in the Bilateral (Original Shell) did not have Femoral neck or stem angle assessed at the baseline.

6. 3 evaluations in the Bilateral (Original Shell) did not have Acetabular cup inclination assessed at the baseline.

Table 10 summarizes the Cox proportional hazards regression analyses for each variable assessed for the Pivotal Unilateral Efficacy (Original Shell), All Enrolled Unilateral (Original Shell) and Bilateral (Original Shell) cohorts. Variables were analyzed and deemed risk factors if the lower bound of the 95% confidence interval for the hazards ratio was ≥ 1. On the basis of that statistical definition of risk factor, eight variables were deemed risk factors:

- female gender,
- small femoral component (≤ 44mm),
- procedures within the surgeon's first 60 cases,
- diagnosis of avascular necrosis, traumatic arthritis, congenital hip dysplasia, or rheumatoid arthritis,
- any previous treatment to the hip,

- multiple femoral cysts,
- acetabular component position of < 30°, and
- any other joint involvement.

Table 10
Cox Regression Hazard Ratios and 95% Confidence Intervals
for Each Potential Revision Risk Factor Evaluated One-at-a-Time

		Pivotal Unilateral Efficacy Cohort (Original Shell)	All Enrolled Unilateral (Original Shell)	Bilateral (Original Shell)
	Revisions	19	36	11
	N = Overall	292	680	203
	N = Month 24+	270	540	160
	%	7.0%	6.7%	6.9%
Female gender	Hazard	2.24	1.63	6.87
	LB	0.91	0.84	1.82
	UB	5.55	3.17	25.96
Non osteoarthritis Dx	Hazard	0.77	1.98	2.17
	LB	0.24	1.00	0.63
	UB	2.42	3.89	7.45
Any Previous Treatment	Hazard	1.33	1.11	5.57
	LB	0.44	0.46	1.19
	UB	4.04	2.68	26.00
Other Joint Involvement	Hazard	1.79	2.61	2.19
	LB	0.70	1.35	0.28
	UB	4.55	5.05	17.15
Femoral Cysts Multiple vs none	Hazard	0.61	0.65	3.43
	LB	0.16	0.30	1.05
	UB	2.37	1.43	11.26
Procedures done within first 60 at a specific site	Hazard	3.68	2.60	7.39
	LB	0.49	1.17	0.92
	UB	27.80	5.77	59.13
Small Femoral Component	Hazard	3.34	2.26	9.73
	LB	1.31	1.17	2.58
	UB	8.50	4.34	36.70
Acetabular Comp. <30° vs not <30°	Hazard	3.04	2.54	6.37
	LB	0.98	0.98	1.59
	UB	9.47	6.61	25.56

In summary, all risk factors pertain to surgical training and technique and/or patient selection. Therefore, obtaining adequate surgeon training, and consideration of these surgical technique and patient selection risks factors may help decrease the risk of device failure.

Survival analyses – All Enrolled Audited Cohort

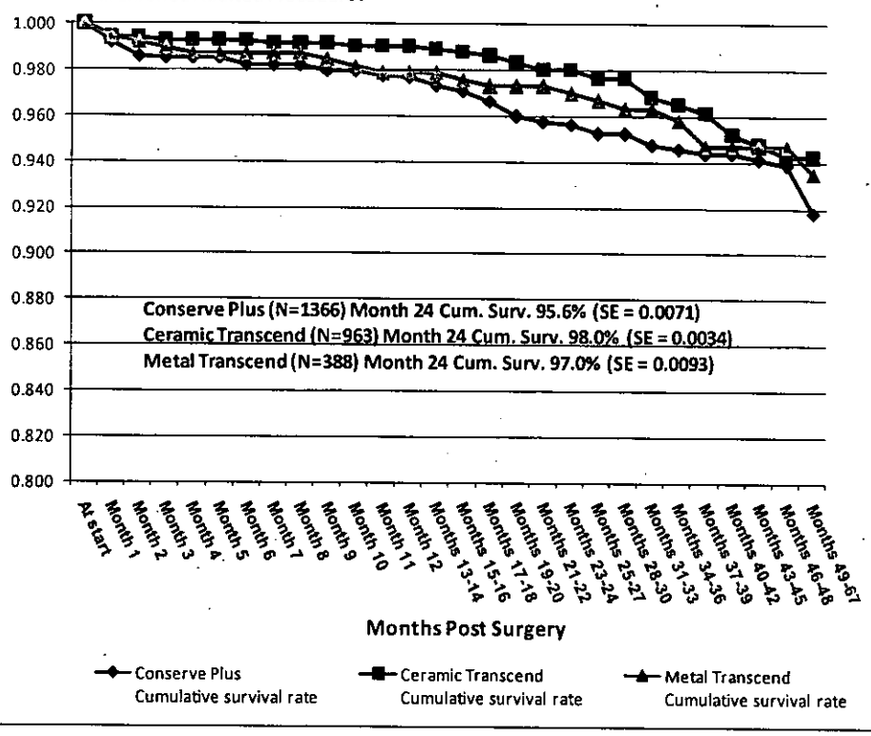
Device survival analyses were performed for the following cohorts:

- CONSERVE® Plus All Enrolled Audited cohort (1366 procedures in 1206 patients) as compared to the Ceramic THR and Metal THR Controls [Table 11].
- CONSERVE® Plus Pivotal Unilateral Efficacy cohort (Original Shell) (N=292 patients) as compared to the Ceramic THR and Metal THR Controls [Table 12].

For each cohort listed above, life-tables were tabulated indicating the number of failures and the number of at-risk procedures over time. Since the number of patients at risk (i.e., being followed) diminishes over time, Peto's method[1] was used to determine standard errors for estimates of cumulative survival. Kaplan-Meier survival curves[2] were plotted on the same graph for the three All Enrolled cohorts in order to facilitate graphical comparisons of survivorship over time.

There was a total of 66 procedures requiring revision, replacement, or removal prior to November 20, 2006 among the 1366 All Enrolled Audited CONSERVE® Plus procedures. Of these, 49 procedures required revision on or before the 2-year anniversary date (i.e., within 730 days of the date of surgery). At the same 2-year timepoint, there were 16 of 963 and 11 of 388 procedures requiring revision, replacement, or removal, in the TRANSCEND® Ceramic and Metal control patients, respectively. Cumulative 2-year survival rates (SE) for CONSERVE® Plus, TRANSCEND® Ceramic, and TRANSCEND® Metal control patients were 0.956 (0.0071), 0.980 (0.0034), and 0.970 (0.0093), respectively (Table 11). The survival distributions did not significantly differ between CONSERVE® Plus and TRANSCEND® Metal controls at two years (log-rank p=0.30) or based on all available follow-up (log-rank p=0.42). In contrast, survival distributions were significantly lower for the CONSERVE® Plus device as compared to the TRANSCEND® Ceramic controls at two years (log-rank p=0.004) as well as based on all available follow-up (p=0.02).

Table 11:
Life Table Analysis (Time to Device Failure (Censoring at Death)
Conserve Plus (N=1366), Ceramic Transcend (N=963) and Metal Transcend (N=388)
All Enrolled Audited Procedures



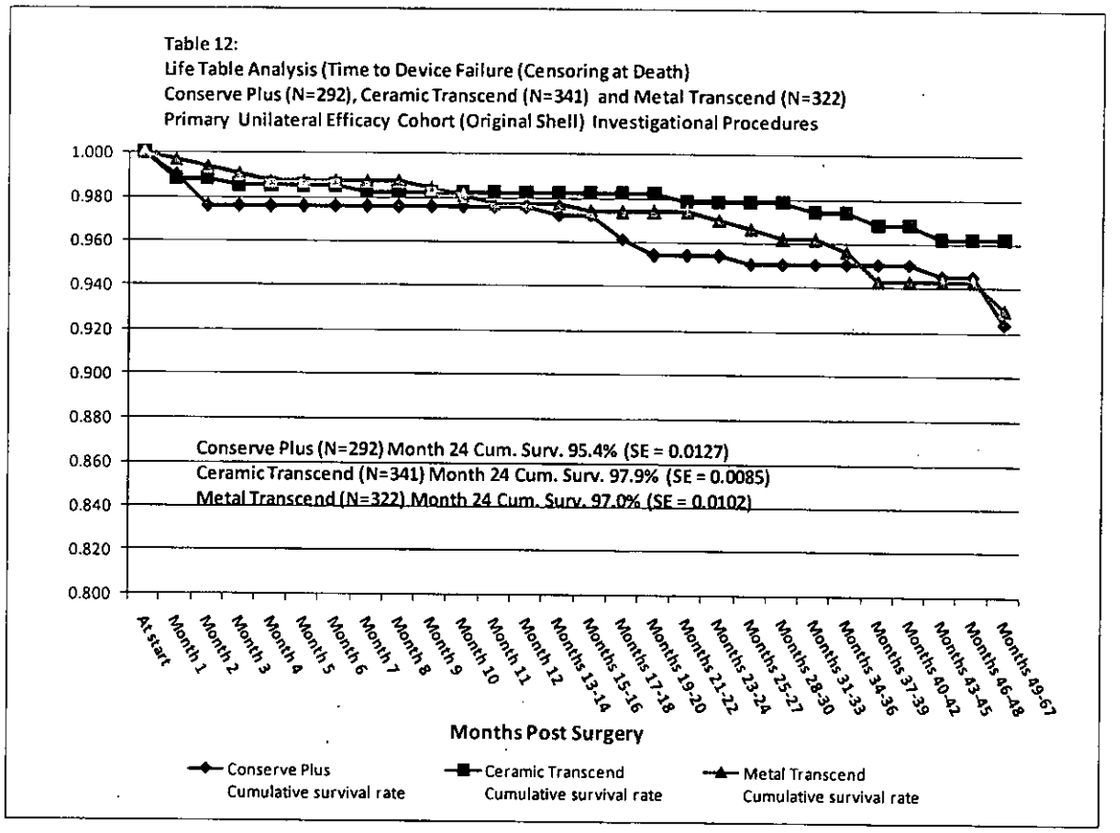
Survival analyses – Pivotal Unilateral Efficacy Cohort (Original Shell)

There was a total of 19 procedures requiring revision, replacement, or removal prior to November 20, 2006 among the 292 Pivotal Unilateral Efficacy cohort (Original Shell) CONSERVE® Plus procedures. Of these, 13 procedures required revision on or before the 2-year anniversary date (i.e., within 730

[1] Peto T, Pike MC, Armitage P, Breslow NE, Cox DR, Howard V, Mantel N, McPherson K, Peto J, and Smith PG. Design and analysis of randomized clinical trials requiring prolonged observation of each patient. II: Analysis and examples. *British Journal of Cancer*, **35**:1-39, 1977.

[2] Kaplan EL and Meier P. Nonparametric estimation from incomplete observations, *Journal of the American Statistical Association*, **53**:45 7-481, 1958.

days of the date of surgery). At the same 2-year timepoint, there were 7 of 341 and 9 of 322 procedures requiring revision, replacement, or removal, in the TRANSCEND® Ceramic and TRANSCEND® Metal control patients, respectively. Cumulative 2-year survival rates (SE) for CONSERVE® Plus, TRANSCEND® Ceramic, and TRANSCEND® Metal control patients were 0.955 (0.0127), 0.979 (0.0085), and 0.970 (0.0102), respectively (Table 12). There were no statistically significant differences in survival rates between Groups.



Summary of adverse events

CONSERVE® Plus (Group I) device-related and other specific adverse events (complications) were compared to the TRANSCEND® Ceramic (Group C1) and TRANSCEND® Metal (Group C2) control groups for the All Enrolled Audited cohorts.

An independent Data Safety Monitoring Board (DSMB) was convened to assess complications for all three device Groups. The DSMB consisted of independent orthopedic surgeons who were not investigators in the CONSERVE® Plus IDE. The approach taken by the DSMB for evaluation of control group complications was to assess severity and relatedness for only those complications deemed to be hip-related by the study investigators. The approach taken by the DSMB for evaluation of investigational group complications was to assess relatedness for all complications and severity for all device/procedure-related complications. The total pool of complications submitted to the DSMB for review included many unrelated to the device or to the surgery. Among this inclusive pool, the primary safety endpoint was defined to be the occurrence of any complication which the DSMB deemed both severe and at least possibly device-related.

Among the All Enrolled Audited procedures, 67 of 1366 (4.9%) CONSERVE® Plus procedures, 29 of 963 (3.0%) TRANSCEND® Ceramic controls, and 20 of 388 (5.2%) TRANSCEND® Metal controls experienced at least one complication assessed by the DSMB as severe and as possibly, probably,

or definitely device-related (Table 13). There was a statistically significantly higher complication rate for the CONSERVE® Plus device as compared to the TRANSCEND® Ceramic control (Fisher's exact test p=0.026). In contrast, there was no statistically significant difference between CONSERVE® Plus and TRANSCEND® Metal (Fisher's exact test p=0.79). For specific hip-related complications that led to these observed differences, please see Table 14.

Table 13:

Comparisons of Summary Complication Rates between All Enrolled Audited cohort and Control Procedures[1]

	All Enrolled Audited (I) (N=1366)		Ceramic THR Control (C1) (N=963)		Metal THR Control (C2) (N=388)		I vs. C1	I vs. C2
	n	%	n	%	n	%	p-value[9]	p-value[9]
Any complication (per procedure)	986	72.2%	438	45.5%	203	52.3%	<0.0001	<0.0001
Any hip related complication[2]	691	50.6%	252	26.2%	129	33.2%	<0.0001	<0.0001
Any device-related complication[3]	302	22.1%	84	8.7%	24	6.2%	<0.0001	<0.0001
Any DSMB device-related complication[4]	531	38.9%	139	14.4%	99	25.5%	<0.0001	<0.0001
Any DSMB procedure-related complication[5]	735	53.8%	203	21.1%	97	25.0%	<0.0001	<0.0001
Any DSMB severe complication[6]	233	17.1%	30	3.1%	20	5.2%	<0.0001	<0.0001
Any DSMB device-related severe complication[7]	**67**	**4.9%**	**29**	**3.0%**	**20**	**5.2%**	**0.026**	**0.793**
Any DSMB procedure-related severe complication[8]	103	7.5%	30	3.1%	20	5.2%	<0.0001	0.115
Deaths	7	0.5%	11	1.1%	3	0.8%	0.097	0.468

Notes:

[1] All procedures meeting inclusion/exclusion criteria with a date of surgery on or before the date of database closure are included in the All Enrolled Procedures Cohorts.

[2] Hip-related defined as all focal hip complications.

[3] Includes complications possibly, probably, or definitely associated with study device as assessed by the investigator.

[4] DSMB independent review that complication was possibly, probably, or definitely associated with study device.

[5] DSMB independent review that complication was possibly, probably, or definitely associated with the implant procedure.

[6] DSMB independent review that complication was severe or life threatening.

[7] DSMB review that complication was possibly, probably, or definitely associated with the study device and was severe or life-threatening.

[8] DSMB review that complication was possibly, probably, or definitely associated with the procedure and was severe or life-threatening.

[9] P-value from pairwise Fisher's Exact test.

Of the 67 procedures reported by the DSMB as severe device-related complications, 57 resulted in device revisions and 10 did not. The 10 procedures that were reported as severe device related but did not lead to revision are as follows:

- 2 with systemic complications.
- 2 with nerve problems.
- 2 with pain in the operative hip.
- 2 with other complications in the operative hip (1 loss of motion and 1 radiation treatment for heterotopic ossification).
- 2 with infection.

The 57 procedures that resulted in revision are identified in Table 8.

There were 7 deaths reported in patients who received the CONSERVE® Plus device. The causes of death are as follows:

- 1 died from a massive cardiac event while bike riding.
- 1 died from a pulmonary embolism that was non-device or procedure related.
- 1 died from a cardiac aneurysm.
- 1 died from a possible heart attack.
- 1 died from lung cancer.
- 1 died from recurrent non-small cell lung cancer.
- 1 died from a drug overdose.

- 1 died from unknown causes.

None of the deaths reported were deemed to be device related.

Hip related adverse events

The tables below provide a breakdown of the overall rates of hip related complications and hip related complications by time of occurrence for the All Enrolled Audited cohort and Pivotal Unilateral Efficacy cohort (Original Shell) and corresponding cohorts of the control groups, (Tables 14, 15, 16, and 17). Hip-related complications were defined as all local hip complications related to the operative hip. DSMB hip-related complications were defined as complications that were possibly, probably, or definitely associated with the operative hip. DSMB hip-related severe complications were defined as complications that were possibly, probably, or definitely associated with the operative hip and were severe or life threatening. The listing of complications includes events related to both the hip and the device. This was done to capture all events associated with the operative hip.

The following hip related AEs were found to be statistically significantly higher for the CONSERVE® Plus All Enrolled Audited cohort when compared to the control group(s).

- 145 procedures with heterotopic ossification when compared to both control groups (p=<0.001); 2/145 (1.4%) were deemed severe.
- 27 procedures with hematoma when compared to the TRANSCEND® Ceramic control (p=0.001); 0/27 (0.0%) were deemed severe.
- 25 procedures with infection: shallow when compared to the TRANSCEND® Ceramic control (p=0.005); 0/25 (0.0%) were deemed severe.
- 25 procedures with loosening of the femoral or acetabular component when compared to the TRANSCEND® Metal control (p=0.017); 22/25 (88.0%) were deemed severe.
- 27 procedures with nerve problems when compared to both control groups (p=0.014 for the TRANSCEND® Ceramic control and p=0.002 for the TRANSCEND® Metal control); 0/27 (0.0%) were deemed severe.
- 367 procedures with pain when compared to both control groups (p=<0.001); 9/367 (2.5%) were deemed severe. Also, reported within this group were 4/367 (1.09%) cases in which clicking, popping, squeaking or grinding was reported with the pain, none were deemed severe.
- 42 procedures with wound problems when compared to both control groups (p=<0.001); 0/42 (0.0%) were deemed severe.
- 201 procedures with other local hip complications when compared to both control groups (p=<0.001); 12/201 (6.0%) were deemed severe. Also, reported within this group were 20/201 (9.95%) cases in which clicking, popping, squeaking or grinding was reported, none were deemed severe.
- 26 procedures with trochanteric bursitis when compared to the TRANSCEND® Metal control (p=0.012); 0/26 (0.0%) were deemed severe.

Table 14:
Specific Complications per Procedure between All Enrolled Audited Cohort (I) and Ceramic THR (C1) and Metal THR (C2) Controls[1]

	All Enrolled Audited (I) (N=1366)		Ceramic THR Control (C1) (N=963)		Metal THR Control (C2) (N=388)		I vs. C1	I vs. C2
	n	%	n	%	n	%	p-value[2]	p-value[2]
Ankylosis	0	0.0%	0	0.0%	3	0.8%	.	0.011
Breakage/fracture of component	7	0.5%	7	0.7%	1	0.3%	0.590	1.000
Dislocation (initial) of component	15	1.1%	16	1.7%	10	2.6%	0.273	0.048
Dislocation (recurrent) of component	4	0.3%	5	0.5%	1	0.3%	0.502	1.000
Fracture of bone	30	2.2%	20	2.1%	6	1.5%	0.886	0.544
Heterotropic ossification	145	10.6%	55	5.7%	18	4.6%	<0.001	<0.001
Hematoma	27	2.0%	4	0.4%	6	1.5%	0.001	0.677
Hemarthrosis	0	0.0%	0	0.0%	3	0.8%	.	0.011
Infection: deep, early<1yr	8	0.6%	7	0.7%	2	0.5%	0.794	1.000
Infection: deep, late>1yr	6	0.4%	2	0.2%	1	0.3%	0.482	1.000
Infection: Shallow	25	1.8%	5	0.5%	8	2.1%	0.005	0.832
Loosening of component	25	1.8%	9	0.9%	1	0.3%	0.081	0.017
Migration of component	7	0.5%	2	0.2%	1	0.3%	0.321	1.000
Nerve problem	27	2.0%	7	0.7%	20	5.2%	0.014	0.002
Pain	367	26.9%	88	9.1%	58	14.9%	<0.001	<0.001
Pain with clicking, popping, squeaking or grinding	4	0.3%	5	0.5%	2	0.5%	0.502	0.619
Perforation	1	0.1%	2	0.2%	0	0.0%	0.573	1.000
Reflex sympathethic dystrophy	0	0.0%	0	0.0%	2	0.5%	.	0.049
Wear of component	0	0.0%	1	0.1%	0	0.0%	0.414	.
Subsidence of component	2	0.1%	4	0.4%	4	1.0%	0.239	0.024
Wound problems	42	3.1%	9	0.9%	0	0.0%	<0.001	<0.001
Other local hip complication	201	14.7%	56	5.8%	26	6.7%	<0.001	<0.001
Clicking, popping, squeaking or grinding	20	1.5%	19	2.0%	2	0.5%	0.413	0.196
Trochanteric bursitis	26	1.9%	35	3.6%	6	1.5%	0.012	0.830
Subluxation	2	0.1%	0	0.0%	1	0.3%	0.515	0.528
Osteolysis	3	0.2%	0	0.0%	1	0.3%	0.272	1.000

Notes:
[1] All procedures meeting inclusion/exclusion criteria with a date of surgery on or before the date of database closure are included in the All Enrolled Audited Cohorts.
[2] Fisher's exact test.

Table 15 :
Specific Complications by Time of Occurrence per Procedure
All Enrolled Audited Cohort (N=1366) (I), Ceramic THR Control (N=963) (C1), and Metal THR Control (N=388) (C2) Procedures

	Pre Discharge			Post Discharge to Month 6			Month 6 to Month 12			Month 12 to Month 24			Month 24 +			Total		
	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2
Ankylosis	0			0			0		2	0		1	0			0	0	3
Breakage/fracture of component	5	5	1	1			0			3	1		3	1		7	7	1
Dislocation (initial) of component	3	2	2	10	11	5	1	1		1	1	2	2	1	1	15	16	10
Dislocation (recurrent) of component	1	1		4	4		0			0			0		1	4	5	1
Fracture of bone	15	15	3	16	3		5			5	1		4	1	3	30	20	6
Heterotropic ossification	13			68	17	2	29	12	3	23	15	9	12	11	4	145	55	18
Hematoma	1		2	23	3	3	1		1	1			2	1		27	4	6
Hemarthrosis	0			0		2	0			0		1	0			0	0	3
Infection: deep, early<1yr	0			6	4	2	2			0	1		0	2		8	7	2
Infection: deep, late>1yr	0			0			0			4	1	1	1	1		6	2	1
Infection, shallow	0			24	3	3	1	2	1	0			0		4	25	5	8
Loosening of component	1			6			3	3		5	3		10	3	1	25	9	1
Migration of component	2			0	1		1			4			1	1	1	7	2	1
Nerve problem	14	2		11	2	2	1	1	5	1		6	0	2	7	27	7	20
Pain	11	3		130	35	17	76	21	12	68	10	9	82	19	20	367	88	58
Pain with clicking, popping, squeaking or grinding	1			0			0			1	1		2	4	2	4	5	2
Perforation	1	2		0			0			0			0			1	2	0
Reflex sympathetic dystrophy	0			0			0			0			0		2	0	0	2
Wear of component	0			0			1			0			0			0	1	0
Subsidence of component	1	1	2	2	2	1	0			1	1	1	1			2	4	4
Wound problems	7			32	8		0			1			2			42	9	0
Other local hip complication	19	4	1	80	14	7	42	12	3	29	13	12	31	13	3	201	56	26
Clicking, popping, squeaking or grinding	2			2	2		5	4		5	2		8	11	2	20	19	2
Trochanteric bursitis	1			10	9	1	6	3	1	5	16		5	7	4	26	35	6
Subluxation	2			2			0			0			0		1	2	0	1
Osteolysis	1			1		1	0			0			1			3	0	1

Table 16
Specific Complications per Procedure between Pivotal Unilateral Efficacy Cohort (Original Shell) (I) versus Ceramic THR (C1) and Metal THR (C2) Controls[1]

	Pivotal Unilateral Efficacy Cohort (I) (Original Shell) (N=292)		Ceramic THR Control (C1) (N=341)		Metal THR Control (C2) (N=322)		I vs. C1	I vs. C2
	n	%	n	%	n	%	p-value[2]	p-value[2]
Ankylosis	0	0.0%	0	0.0%	3	0.9%	.	0.251
Breakage/fracture of component	3	1.0%	4	1.2%	1	0.3%	1.000	0.351
Dislocation (initial) of component	3	1.0%	4	1.2%	9	2.8%	1.000	0.148
Dislocation (recurrent) of component	1	0.3%	1	0.3%	1	0.3%	1.000	1.000
Fracture of bone	11	3.8%	7	2.1%	6	1.9%	0.234	0.218
Heterotropic ossification	44	15.1%	23	6.7%	15	4.7%	0.0007	<0.001
Hematoma	3	1.0%	1	0.3%	6	1.9%	0.340	0.509
Hemarthrosis	0	0.0%	0	0.0%	2	0.6%	.	0.500
Infection: deep, early<1yr	1	0.3%	1	0.3%	2	0.6%	1.000	1.000
Infection: deep, late>1yr	1	0.3%	1	0.3%	1	0.3%	1.000	1.000
Infection: Shallow	4	1.4%	2	0.6%	7	2.2%	0.422	0.551
Loosening of component	6	2.1%	1	0.3%	1	0.3%	0.053	0.058
Migration of component	0	0.0%	2	0.6%	1	0.3%	0.502	1.000
Nerve problem	3	1.0%	3	0.9%	14	4.3%	1.000	0.013
Pain	87	29.8%	39	11.4%	50	15.5%	<0.001	<0.001
Pain with clicking, popping, squeaking or grinding	2	0.7%	1	0.3%	2	0.6%	0.598	1.000
Perforation	0	0.0%	0	0.0%	0	0.0%	.	.
Reflex sympathethic dystrophy	0	0.0%	0	0.0%	2	0.6%	.	0.500
Wear of component	0	0.0%	1	0.3%	0	0.0%	1.000	.
Subsidence of component	1	0.3%	3	0.9%	4	1.2%	0.628	0.376
Wound problems	6	2.1%	4	1.2%	0	0.0%	0.525	0.011
Other local hip complication	55	18.8%	23	6.7%	23	7.1%	<0.001	<0.001
Clicking, popping, squeaking or grinding	6	2.1%	10	1.0%	2	0.6%	0.614	0.159
Trochanteric bursitis	10	3.4%	18	5.3%	6	1.9%	0.333	0.311
Subluxation	1	0.3%	0	0.0%	0	0.0%	0.461	0.476
Osteolysis	2	0.7%	0	0.0%	1	0.3%	0.212	0.607

Notes:
[1] Pivotal unilateral efficacy cohort, ceramic THR primary unilateral efficacy cohort, and all metal THR unilateral procedures.
[2] Fisher's exact test.

Table 17 :
Specific Complications by Time of Occurrence per Procedure
Pivotal Unilateral Efficacy Cohort (Original Shell) (N=292) (I), Ceramic THR Control (N=341) (C1), and Metal THR Control (N=322) (C2) Procedures

	Pre Discharge			Post Discharge to Month 6			Month 6 to Month 12			Month 12 to Month 24			Month 24 +			Total		
	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2	I	C1	C2
Ankylosis									2						1	0	0	3
Breakage/fracture of component		4	1							2						3	4	1
Dislocation (initial) of component	1	2	1	1	2	5				1		1			2	3	4	9
Dislocation (recurrent) of component		1		1								1				1	1	1
Fracture of bone		6	3	8			1				1	3	3			11	7	6
Heterotropic ossification				20	6	1	12	6	3	5	5	4	7	6	7	44	23	15
Hematoma			2	3		3	1		1		1					3	1	6
Hemarthrosis						2										0	0	2
Infection: deep, early<1yr				1	1	2										1	1	2
Infection: deep, late>1yr										1	1				1	1	1	1
Infection, shallow				4	1	2	1	1				4				4	2	7
Loosening of component				1						3		1	2	1		6	1	1
Migration of component					1						1	1				0	2	1
Nerve problem	2	2		4	1	1			3			5	3		5	3	3	14
Pain[1]	5	1		22	13	15	14	11	10	35	8	18	11	6	7	87	39	50
Pain with clicking, popping, squeaking or grinding				1						2	1		1		2	2	1	2
Perforation																0	0	0
Reflex sympathetic dystrophy												2				0	0	2
Wear of component								1								0	1	0
Subsidence of component	1	1	2	1	1					1				1	1	3	3	4
Wound problems				6	4											6	4	0
Other local hip complication[2]	4		1	16	5	7	13	4	3	11	10	3	11	4	9	55	23	23
Clicking, popping, squeaking or grinding				2	1			1		2			2	8	2	6	10	2
Trochanteric bursitis				13	3	1	2	1	1	4	5	4	1	9		10	18	6
Subluxation				1												1	0	0
Osteolysis				1		1										2	0	1

Device related adverse events

Device related adverse events were defined as post-operative complications concerning the device related to the design, and/or material composition of the implant and implantation technique. DSMB device-related complications were defined as complications that were possibly, probably, or definitely associated with the study device. DSMB device-related severe complications were defined as complications that were possibly, probably, or definitely associated with the study device and were severe or life threatening. The table below provides a breakdown of the rates of severe device related complications for the All Enrolled Audited cohort and the corresponding cohorts of the control groups (Table 18).

It should be noted that some device related adverse events reported in Table 18 did not result in revision during the course of the clinical study; therefore, do not appear in Table 8 above. In addition, some of the reasons for device revision were non-device related. Of the 28 fractures of bone reported in Table 8, 26 were deemed to be device related by the DSMB. The 2 remaining fractures of bone were not deemed device related because the fractures were the result of trauma. Twenty-two loosenings of component were reported in Table 18. All of these components were revised but in Table 8 the reasons for revision were reported as follows: 17 revised due to loosening of either the acetabular (10) or femoral component (7); one revised due to acetabular component loosening with femoral neck fracture; three loosenings were revised due to infection; and, 1 patient had a second surgery to reposition a loosened acetabular cup 2 days after the initial procedure.

As shown in Table 18, one procedure had recurrent dislocation. To date, this device has not been revised and, therefore, would not appear in Table 8. Table 8 also reports 8 procedures being revised due to infection. One procedure presented with deep, late (> 1 year) infection that was deemed by the DSMB as device related, with the remaining 7 being deemed not device-related.

Table 18 reports 5 "breakage/fracture of component" serious device-related complications. For all 5 reports, the femoral stem broke secondary to femoral neck fracture. It should be noted that there were 7 total "breakage /fracture of component" reported on Table 14, 2 of which were not deemed device related due to trauma. Also, the 11 reported severe device-related "Other local complications" include the following:

- 1 episode of device clunking with sore back.
- 1 surgery to remove scar tissue with the device remaining implanted.
- 1 case of pseudocapsule release and release of flexors and abductors due to no motion at hip.
- 1 patient underwent radiation therapy following removal of heterotopic ossification.
- 1 patient had severe stiffness that prevented patient from returning to work.
- 1 patient had deformation of the femoral component (stem bent secondary to femoral neck fracture).
- 1 patient had pain secondary to impingement.
- 1 patient reported increased resistance hip motion.
- 1 patient presented with protrusion of the acetabular cup through the acetabulum.
- 1 patient heard a pop when bending over.
- 1 patient reported revision, but refused to give information on the cause.

Table 18:

Pairwise Comparisons Between All Enrolled Audited Cohort and Control Procedures[1]
Specific DSMB Assessed Severe Device-Related Complication Rates Per Procedure

	All Enrolled Audited (I) (N=1366)		Ceramic THR Control (C1) (N=963)		Metal THR Control (C2) (N=388)		I vs. C1	I vs. C2
	n	%	n	%	n	%	p-value[2]	p-value[2]
Ankylosis	0	0.0%	0	0.0%	3	0.8%	.	0.011
Breakage/fracture of component	5	0.4%	3	0.3%	0	0.0%	1.000	0.593
Dislocation (initial) of component	0	0.0%	1	0.1%	2	0.5%	0.413	0.049
Dislocation (recurrent) of component	1	0.1%	2	0.2%	0	0.0%	0.573	1.000
Fracture of bone	26	1.9%	1	0.1%	1	0.3%	<0.0001	0.017
Heterotropic ossification	2	0.1%	1	0.1%	1	0.3%	1.000	0.528
Hematoma	0	0.0%	0	0.0%	0	0.0%	.	.
Hemarthrosis	0	0.0%	0	0.0%	0	0.0%	.	.
Infection: deep, early<1yr	0	0.0%	0	0.0%	0	0.0%	.	.
Infection: deep, late>1yr	1	0.1%	0	0.0%	0	0.0%	1.000	1.000
Infection: Shallow	0	0.0%	0	0.0%	6	1.5%	.	<0.001
Loosening of component	22	1.6%	8	0.8%	1	0.3%	0.134	0.041
Migration of component	4	0.3%	1	0.1%	0	0.0%	0.655	0.582
Nerve problem	0	0.0%	0	0.0%	2	0.5%	.	0.049
Pain	8	0.6%	3	0.3%	1	0.3%	0.541	0.693
Perforation	1	0.1%	0	0.0%	0	0.0%	1.000	1.000
Reflex sympathethic dystrophy	0	0.0%	0	0.0%	0	0.0%	.	.
Wear of component	0	0.0%	1	0.1%	0	0.0%	0.413	.
Subsidence of component	1	0.1%	2	0.2%	0	0.0%	0.573	1.000
Wound problems	0	0.0%	0	0.0%	0	0.0%	.	.
Other local hip complication	11	0.8%	0	0.0%	0	0.0%	0.004	0.136
Trochanteric bursitis	0	0.0%	0	0.0%	0	0.0%	.	.
Subluxation	0	0.0%	0	0.0%	0	0.0%	.	.
Osteolysis	1	0.1%	0	0.0%	0	0.0%	1.000	1.000

Notes:

[1] All procedures meeting inclusion/exclusion criteria with a date of surgery on or before the date of database closure are included in the All Enrolled Audited Cohort.

[2] Fishers Exact test.

Systemic events

Systemic adverse events were those reported events that did not relate directly to the operation or the operative site/device.

The table below provides a summary of the systemic complications for the CONSERVE® Plus All Enrolled Audited (Group I) procedures and the corresponding cohorts of the TRANSCEND® Ceramic (Group C1) and TRANSCEND® Metal (Group C2) control groups (Table 19). Although statistically significant differences were identified between groups for certain systemic complications, none were device-related.

Table 19:
Comparisons of Percentages with Specific Complications between All Enrolled Investigational Device and Control Procedures[1]

	Investigational Device (I) (N=1366)		Ceramic THR Control (C1) (N=963)		Metal THR Control (C2) (N=388)		I vs. C1	I vs. C2
	n	%	n	%	n	%	p-value[2]	p-value[2]
Systemic								
Allergic reactions	19	1.6%	4	0.5%	1	0.3%	0.019	0.061
Disseminated intravascular coagulation	0	0.0%	1	0.1%	2	0.6%	0.412	0.052
Fat embolism	1	0.1%	0	0.0%	3	0.8%	1.000	0.039
Gastrointestinal	36	3.0%	14	1.7%	8	2.2%	0.059	0.585
Genitourinary disorders	45	3.7%	15	1.8%	1	0.3%	0.011	<0.001
Metabolic disorders	4	0.3%	0	0.0%	7	2.0%	0.148	0.004
Myocardial infarction	2	0.2%	5	0.6%	5	1.4%	0.132	0.008
Stroke	1	0.1%	1	0.1%	62	17.4%	1.000	<0.0001
Other cardiovascular	36	3.0%	15	1.8%	4	1.1%	0.112	0.055
Pulmonary embolism	5	0.4%	4	0.5%	1	0.3%	1.000	1.000
Other respiratory	16	1.3%	10	1.2%	7	2.0%	0.843	0.451
Septicemia	1	0.1%	1	0.1%	3	0.8%	1.000	0.039
Thrombosis	18	1.5%	6	0.7%	3	0.8%	0.143	0.441
Other systemic complication	145	12.0%	88	10.4%	8	2.2%	0.289	<0.0001

Notes:
[1] All procedures meeting inclusion/exclusion criteria with a date of surgery on or before the date of database closure are included in the All Enrolled Procedures Cohorts.
[2] Fisher's exact test

Systemic complications that demonstrated a statistical difference were seen in the following categories: allergic reactions, gastrointestinal disorders, genitourinary disorders, other cardiovascular disorders and other systemic complications. These are general categories used for analytical purposes. The actual events associated with these general categories are as follows:

- 19 allergic reactions (i.e., rash, dermatitis); None were reported as severe.
- 36 gastrointestinal (i.e., nausea, vomiting, rectal bleeding, diarrhea, abdominal pain, constipation); None were reported as severe.
- 45 genitourinary disorders (i.e., urinary tract infection, urinary retention, kidney stones, prostate cancer, benign prostate hypertrophy); None were reported as severe.
- 36 cardiovascular events (e.g., chest pain, tachycardia, atrial fibrillation, abnormal EKG, coronary artery disease, cardiac aneurysm resulting in death, 2 heart attacks resulting in death); 3/36 (8.3%) were reported as severe.
- 145 Other systemic complications (e.g., anemia, swelling in extremities, fever, edema, headache, metastatic lung cancer resulting in death, and Cause of Death unknown); 2/145 (1.4%) were reported as severe.

Metal ions

While concerns exist with regard to the local and systemic effects of metal ions, there is no direct evidence linking metal-on-metal arthroplasty with long-term medical problems. A study performed on 25 patients with the CONSERVE® Plus Total Resurfacing Hip System was reported by Skipor, and co-workers in, "Serum and urine metal levels in patients with metal-on-metal surface arthroplasty," *J Mat Sci Mat Med* 13 (2002), p.1227-34. Head sizes for these patients ranged from 38 to 52mm. Serum cobalt and chromium and urine chromium analysis revealed levels that do not differ widely from metal-on-metal values reported in the literature, although they are higher than other bearings. Mean serum cobalt and chromium at 12 months were 1.07 (+/- 0.26) and 1.80 (+/- 0.45) parts per billion (ppb), respectively. Mean urine chromium at 12 months was 2.21 (+/- 0.83) ppb. In summary,

while ions will be higher in patients who receive metal-on-metal hip implants versus patients who receive other bearing surfaces (i.e., metal-on-polyethylene, ceramic-on-ceramic), there is no direct evidence demonstrating that elevated levels adversely effect health.

The Oxford research group presented their findings related to 115 cases in which 6 patients (5 female, 1 male) implanted with 9 hips (3 bilateral, 3 unilateral) presented with 9 pseudotumors and higher median serum cobalt and serum chromium ion levels as compared to those cases without pseudotumors. Moreover, two of these 9 pseudotumors exhibited signs of lymphocyte infiltration indicative of delayed hypersensitivity reaction (ALVAL). This led the authors to conclude that "an asymptomatic pseudotumour in patients with metal-on-metal hip resurfacing is associated with elevated serum cobalt and chromium ion levels, suggesting that abnormal wear may be the cause of pseudotumour. The precise mechanism is unclear and may be due to metal hypersensitivity reaction or toxic effects. "Metal Ion Levels In Asymptomatic Pseudotumours Associated With Metal-on-metal Hip Resurfacings." Kwon, et. al. Paper No. 44, *55th Annual Meeting of the Orthopaedic Research Society, Las Vegas, 2009.*

Effectiveness Data

Effectiveness was evaluated primarily by the Composite Clinical Success (CCS) definition. Harris Hip Score, radiographic outcome, and Health Related Quality of Life (SF-12) Scores were also evaluated as a measure of effectiveness.

Harris Hip Score

As seen in Table 20, the mean Month 24+ Harris Hip Total score was 94.4 in the CONSERVE® Plus Pivotal Unilateral Efficacy cohort (Original Shell). This compares to 94.1 and 92.7 for patients in the TRANSCEND® Ceramic and Metal THR Unilateral Control cohorts, respectively.

Mean 24+ Harris Hip function score was 45.1, 44.4 and 43.4, for CONSERVE® Plus Pivotal Unilateral Efficacy (Original Shell), TRANSCEND® Ceramic, and TRANSCEND® Metal Unilateral control cohorts, respectively.

Mean 24+ Harris Hip Range of Motion (ROM) score was 4.82, 4.88, and 4.81 for the CONSERVE® Plus Pivotal Unilateral Efficacy (Original Shell), TRANSCEND® Ceramic, and TRANSCEND® Metal Unilateral control cohorts, respectively.

Table 20
Mean Harris Hip Total, Function, and ROM Scores Over Time
Pivotal Unilateral Efficacy Cohort (Original Shell) (I) vs. Ceramic THR (C1) and Metal THR Controls (C2)

	Pivotal Unilateral Efficacy Cohort (I) Harris Hip Total Score[1]					Ceramic Transcend Control (C1) Harris Hip Total Score[1]					Metal Transcend Control (C2) Harris Hip Total Score[1]					T-Test	
	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	I vs. C1 p-value[2]	I vs. C2 p-value[2]
Pre-0p	290	49.4	11.7	7.3	77.9	337	45.2	12.8	12.9	89.0	316	47.6	14.2	4.5	89.7	<0.001	0.086
Month 6	204	91.4	9.7	49.0	100.0	291	88.3	13.0	37.7	100.0	257	88.4	13.9	13.6	100.0	0.002	0.006
Month 12	239	93.4	9.7	38.8	100.0	255	92.3	13.0	23.9	100.0	223	91.4	12.0	26.7	100.0	0.272	0.053
Month 24	226	94.9	7.7	59.0	100.0	207	94.4	10.0	33.7	100.0	207	93.1	10.0	38.0	100.0	0.595	0.043
Month 24+	264	94.4	8.5	49.8	100.0	278	94.1	10.8	33.7	100.0	267	92.7	10.7	38.0	100.0	0.727	0.041
	Pivotal Unilateral Efficacy Cohort (I) Harris Hip Function Score					Ceramic Transcend Control (C1) Harris Hip Function Score					Metal Transcend Control (C2) Harris Hip Function Score						
	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	I vs. C1 p-value[2]	I vs. C2 p-value[2]
Pre-0p	291	27.6	8.0	0.0	44.0	337	25.2	8.3	4.0	45.0	316	25.4	8.6	0.0	42.0	<0.001	0.001
Month 6	205	43.0	5.5	5.0	47.0	291	40.2	7.7	7.0	47.0	257	40.1	8.2	5.0	47.0	<0.001	<0.001
Month 12	239	44.6	4.6	14.0	47.0	255	43.4	6.4	5.0	47.0	223	42.6	6.0	8.0	47.0	0.013	<0.001
Month 24	226	45.3	3.4	20.0	47.0	207	44.5	5.3	15.0	47.0	207	43.3	5.1	19.0	47.0	0.070	<0.001
Month 24+	264	45.1	3.5	20.0	47.0	278	44.4	5.4	15.0	47.0	267	43.4	5.1	19.0	47.0	0.076	<0.001
	Pivotal Unilateral Efficacy Cohort (I) Harris Hip ROM Score1					Ceramic Transcend Control (C1) Harris Hip ROM Score1					Metal Transcend Control (C2) Harris Hip ROM Score1						
	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	I vs. C1 p-value[2]	I vs. C2 p-value[2]
Pre-0p	291	4.47	0.61	0.00	5.00	338	4.09	0.97	0.00	5.00	316	4.30	0.60	0.00	5.00	<0.001	<0.001
Month 6	207	4.79	0.77	0.00	5.00	291	4.77	0.33	1.08	5.00	258	4.80	0.36	0.00	5.00	0.824	0.855
Month 12	241	4.89	0.36	0.00	5.00	255	4.82	0.36	0.00	5.00	226	4.85	0.14	4.10	5.00	0.018	0.068
Month 24	229	4.81	0.75	0.00	5.00	207	4.88	0.15	4.23	5.00	207	4.84	0.37	0.00	5.00	0.178	0.658
Month 24+	265	4.82	0.76	0.00	5.00	278	4.88	0.15	4.23	5.00	267	4.81	0.54	0.00	5.00	0.171	0.854

Notes: [1] Post-op Harris Hip Total and ROM scores include procedures with zeros imputed for missing HHS ROM and deformity.
[2] T-Test (Pooled standard error for equal variance and Satterthwaite standard error for unequal variance).

There were 11 hips in the CONSERVE® Plus Pivotal Unilateral Efficacy cohort (Original Shell) that had a Harris Hip Total score <70 at 24+ Months. Of these, 1 hip was painful due to a loose acetabular cup, 3 had sciatica, 1 had cardiovascular complications unrelated to the hip, 1 had hip and knee pain, and 1 had degenerative spondylolisthesis. For 4 of the 11, no reason for the "poor" rating was ascertained.

No statistical differences were seen in the Month 24 and Month 24+ postoperative range of motion values when compared to both control cohorts.

Radiographic outcomes

Radiographic outcomes for the Pivotal Unilateral Efficacy cohort (Original Shell) were summarized based on independent radiographic evaluations as well as investigator evaluation (Tables 21 and 22, respectively). In both cases, the Month 24 cumulative radiolucency summary was computed by categorizing the most severe radiolucencies across zones and time intervals. A cumulative radiolucency was defined as the largest radiolucency identified over time up until and including the Month 24 timepoint.

There were 275 out of 292 Pivotal Study Unilateral (Original Shell) cohort patients with at least one independent radiographic evaluation. In 31 of 275 patients (11.3%) cumulative radiolucencies greater than 2 mm were identified; however, there were no revisions or removals reported within this group. In 26 of 275 (9.5%) cases, cumulative radiolucencies >1 to 2 mm were reported. There was one failure identified in this group due to impingement and not as a result of loosening or migration.

There were 288 out of 292 Pivotal Study Unilateral Patients with at least one investigator-based follow-up radiograph. In 6 of 288 patients (2.1%), cumulative radiolucencies greater than 2 mm were identified. There were no revisions or removals reported within this group. In 11 of 288 (3.8%)

patients, radiolucencies >1 to 2mm were reported. There was one failure identified in this group due to impingement and not as a result of loosening or migration. Note: This is the same patient who was reviewed during the independent radiographic assessment.

There were no cases of migration of the cup reported by the independent radiographic reviewer or investigator for the Pivotal Study Unilateral (Original Shell) cohort patients.

In terms of the composite clinical success (CCS) radiographic endpoint, a patient was defined as a success at the Month 24+ follow-up timepoint if there was an absence of complete radiolucency in all four radiographic views. Complete radiolucency in a view was defined to be present if there was any radiolucency present in all zones comprising that view. There was one case of complete radiolucency as identified by the investigator at Month 24 in the Pivotal Study Unilateral (Original Shell) cohort. This patient went on to be revised for acetabular cup loosening.

In addition to the CCS radiographic findings, it was noted that in the Pivotal Study Unilateral (Original Shell) cohort there was 1 case revised due to femoral loosening (Table 8), in which no radiolucencies were identified by independent or investigator radiographic review. There were 3 cases revised due to acetabular loosening (Table 8) in which no radiolucencies were identified by independent radiographic review. As noted in the CCS radiographic findings above, one of these three cases reported complete radiolucency as identified by the investigator at Month 24. This case had radiolucencies (0 to 1mm) identified in all 3 Charnley zones.

Table 21:
Overall Interval Specific and Cumulative Summary of Any Finding of Acetabular or Femoral Radiolucency Pivotal Study Unilateral Efficacy Cohort (Original Shell) {Independent radiography}

Interval	N	None	>0-1	>1-2	>2	Any
Immed Post-Op	192	146 [76.0%]	25 [13.0%]	12 [6.3%]	9 [4.7%]	46 [24.0%]
Month 6	202	169 [83.7%]	10 [5.0%]	13 [6.4%]	10 [5.0%]	33 [16.3%]
Month 12	219	189 [86.3%]	10 [4.6%]	7 [3.2%]	13 [5.9%]	30 [13.7%]
Month 24	219	164 [74.9%]	24 [11.0%]	9 [4.1%]	22 [10.0%]	55 [25.1%]
Cumulative[1]	275	169 [61.5%]	49 [17.8%]	26 [9.5%]	31 [11.3%]	106 [38.5%]
Month 36	36	23 [63.9%]	6 [16.7%]	4 [11.1%]	3 [8.3%]	13 [36.1%]

Notes:
[1] - Cumulative based on worst result over time up to Month 24.

Table 22:
Overall Interval Specific and Cumulative Summary of Any Finding of Acetabular or Femoral Radiolucency Pivotal Study Unilateral Efficacy Cohort (Original Shell) {Investigator-based}

Interval	N	None	>0-1	>1-2	>2	Any
Immed Post-Op	221	208 [94.1%]	11 [5.0%]	1 [0.5%]	1 [0.5%]	13 [5.9%]
Month 6	229	214 [93.4%]	10 [4.4%]	3 [1.3%]	2 [0.9%]	15 [6.6%]
Month 12	243	214 [88.1%]	21 [8.6%]	5 [2.1%]	3 [1.2%]	29 [11.9%]
Month 24	229	174 [76.0%]	47 [20.5%]	4 [1.7%]	4 [1.7%]	55 [24.0%]
Cumulative[1]	288	215 [74.7%]	56 [19.4%]	11 [3.8%]	6 [2.1%]	73 [25.3%]
Month 36	169	123 [72.8%]	37 [21.9%]	5 [3.0%]	4 [2.4%]	46 [27.2%]

Notes:
[1] - Cumulative based on worst result over time up to Month 24.

As noted in Tables 21 and 22, the use of independent radiographic results when defining success or failure in terms of the primary composite clinical success (CCS) endpoint did not significantly alter the results of the primary non-inferiority comparisons.

Health Related Quality of Life (SF-12)

The Physical Component Summary (PCS) and Mental Health Component Summary (MCS) were determined from the SF-12, a well-known generic health-related quality of life instrument. Raw scores were converted to US population-based age and gender adjusted z-scores. These z-scores reflect percentile values with reference to the US population. Comparisons between the CONSERVE® Plus Pivotal Unilateral Efficacy cohort (Original Shell) and the respective cohorts for the TRANSCEND® Ceramic and TRANSCEND® Metal THR control devices are summarized in Table 23 below.

Table 23

Descriptive Comparisons of Health-Related Quality of Life Age-Adjusted SF-12 PCS and MCS Z-Scores[1]
Summary Statistics Prior to Surgery, Month 24+, and Change Score by Device Group
Pivotal Unilateral Efficacy Cohort (Original Shell) (I), Ceramic (C1), and Metal (C2) THR Unilateral Controls

			Pre-Surgery z-score			Month 24+[2] z-score			Change from Baseline		
SF-12	Device	N	Mean	SD	Median	Mean	SD	Median	Mean	SD	Median
SF-12 PCS z-score[3]	I	263	-1.82	1.19	-1.93	0.33	0.82	0.66	2.15	1.24	2.32
	C1	263	-1.88	1.09	-1.78	0.07	1.13	0.55	1.95	1.17	1.94
	C2	254	-1.85	1.18	-1.84	-0.03	1.20	0.40	1.82	1.29	1.96
SF-12 MCS z-score[4]	I	263	0.00	1.16	0.25	0.55	0.66	0.76	0.55	1.13	0.35
	C1	263	0.05	1.18	0.30	0.54	0.82	0.76	0.50	1.15	0.31
	C2	254	-0.01	1.10	0.10	0.43	0.89	0.72	0.43	1.21	0.31

[1] Z-scores are age adjusted and reflect deviations from U.S. population age specific normative values contained in Tables 7.4 to 7.9 (pages 36 – 41) of the SF-12 scoring manual.

[2] Month 24+ values are from Month 24 or if Month 24 SF-12 was missing, from the first available subsequent values.

[3] PCS is the SF-12 Physical Component Score. Z-scores were computed by subtracting age specific normative mean values and then dividing by age specific normative standard deviations.

[4] MCS is the SF-12 Mental Health Component Score. Z-scores were computed by subtracting age specific normative mean values and then dividing by age specific normative standard deviations.

Preoperative mean PCS z-scores across CONSERVE® Plus (Group I), and TRANSCEND® Ceramic (Group C1) and TRANSCEND® Metal (Group C2) controls were approximately equivalent to the third (3rd) percentile values relative to US national normative data. This demonstrates that patients in all three device groups are at the lowest end of the normative physical spectrum and have profound physical deficits. At Month 24+, mean PCS z-scores increased in all Groups reflecting large improvements in physical HRQoL in all three groups. Controlling for baseline PCS z-scores, statistically significant differences were identified with respect to mean improvement at Month 24+ between CONSERVE® Plus and TRANSCEND® Ceramic ($p=0.003$) and CONSERVE® Plus and TRANSCEND® Metal ($p<0.001$).

Preoperative mean MCS z-scores across all Groups did not show mental deficits relative to the US national reference norms, as was the case with the physical scores. At Month 24+, however, improvement was still seen in mental scores for all Groups, but there were no significant differences between Groups.

Composite Clinical Success (CCS)

Table 24 below provides the comparison of CCS between Groups based on various a assumptions regarding follow-up interval definitions, imputations for HHS ROM/deformity scores, and radiographic review source. The highlighted row shows that 152 of 199 (76.4%) Pivotal Unilateral Efficacy cohort (Original Shell) procedures achieved Month 24+ CCS. In comparison, 153 of 202 (75.7%) procedures in the TRANSCEND® Ceramic Control Primary Efficacy cohort and 139 of 203 (68.5%) TRANSCEND® Metal Control Primary Efficacy cohort procedures achieved CCS at Month 24+. Non-

inferiority of the investigational device relative to both control cohorts was demonstrated because the lower bound of the 95% confidence interval exceeded -0.08 (or -8%), which was the pre-specified margin of non-inferiority. Non-inferiority was also met in all other analysis cohorts.

Table 24
Comparisons with THR Controls: Composite Clinical Success (CCS) at Month 24+[1]
For Different Assumptions Regarding Interval Definitions, Imputations, and Radiography Source

	Pivotal Unilateral Efficacy Cohort (Original Shell) (I)			Ceramic THR Control (C1)			Metal THR Control (C2)			I vs. C1		I vs. C2	
	n	N	Prop.	n	N	Prop.	n	N	Prop.	Diff.	95% CI LB[5]	Diff.	95% CI LB[5]
All evaluated[2] (Actual[B]), ROM/deformity imputaton[3], investigator radiography	211	270	0.781	197	260	0.758	175	249	0.703	0.024	-0.036	0.079	0.016
Within interval[4] (Actual[A]), ROM/deformity imputation[3], investigator radiography	194	252	0.770	153	202	0.757	139	202	0.688	0.012	-0.054	0.082	0.013
All evaluated[2] (Actual[B]), ROM/deformity imputation disabled, investigator radiography	208	267	0.779	197	260	0.758	174	246	0.707	0.021	-0.039	0.072	0.008
Within interval[4] (Actual[A]), ROM/deformity imputation disabled, investigator radiography	190	248	0.766	153	202	0.757	139	203	0.685	0.009	-0.058	0.081	0.012
Within interval[4] (Actual[A]), ROM/deformity imputation disabled, independent radiography	152	199	0.764	153	202	0.757	139	203	0.685	0.006	-0.064	0.079	0.006

[1] For Month 24+ CCS, missing Month 24 endpoints were replaced by endpoints from subsequent evaluations if available.

[2] WMT defined All Evaluated (Actual[B]) intervals as follows: Pre-op< 0 days post surgery; Immed. interval 1-45 days; 6 Mo. Interval 46-210 days; 1 Yr Interval 211-425 days; 2 Yr Interval 426-790 days.

[3] ROM/deformity imputations. When Harris Hip Scores were otherwise complete, missing ROM was set to 0 of 5 points and/or missing deformity was to 0 of 4 points, reducing the maximum HHS to 95, 96, or 91 (when both were missing) points.

[4] Within interval (Actual[A]) analyses based on Guidance for Industry and FDA Staff Clinical Data Presentations for Orthopedic Device Applications Document issued on: December 2, 2004 by FDA Center for Devices and Radiological Health, Orthopedic Devices Branch, Office of Device Evaluation, page 1. The 2 Yr interval is (24+/-2 mo.).

[5] Lower bounds of 1-sided 95% confidence intervals for true differences between Conserve Plus and the control groups. The study was designed to demonstrate clinical non-inferiority defined as a success rate that was, at most, 0.08 less than control.

HANDLING AND STERILIZATION

The implants described in this package insert are provided sterile as indicated on the individual product's label.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

Implants are for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

Surgical instruments should be cleaned and sterilized according to the following parameters:

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.

8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens; however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

The minimum recommended steam sterilization conditions for Wright reusable instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.

2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Gravity Displacement 250 °F (121°C)	Exposure Temperature	250°F (121°C)
	Exposure Time	30 minutes
	Dry Time	15 minutes
Gravity Displacement 270 °F (132 °C)	Exposure Temperature	270°F (132°C)
	Exposure Time	10 minutes
	Dry Time	15 minutes
Prevacuum 270 °F (132 °C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from it packaging using accepted sterile technique with powder-free gloves. Ensure that the component is at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI guidelines and have been developed and tested using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

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

The CONSERVE® PLUS Femoral Component is for use with CEMENT USE ONLY.

The CONSERVE® PLUS Acetabular Component is for use with NON-CEMENT USE ONLY.

Patents:
One or more of the following patents may apply to Wright Medical Technology products:

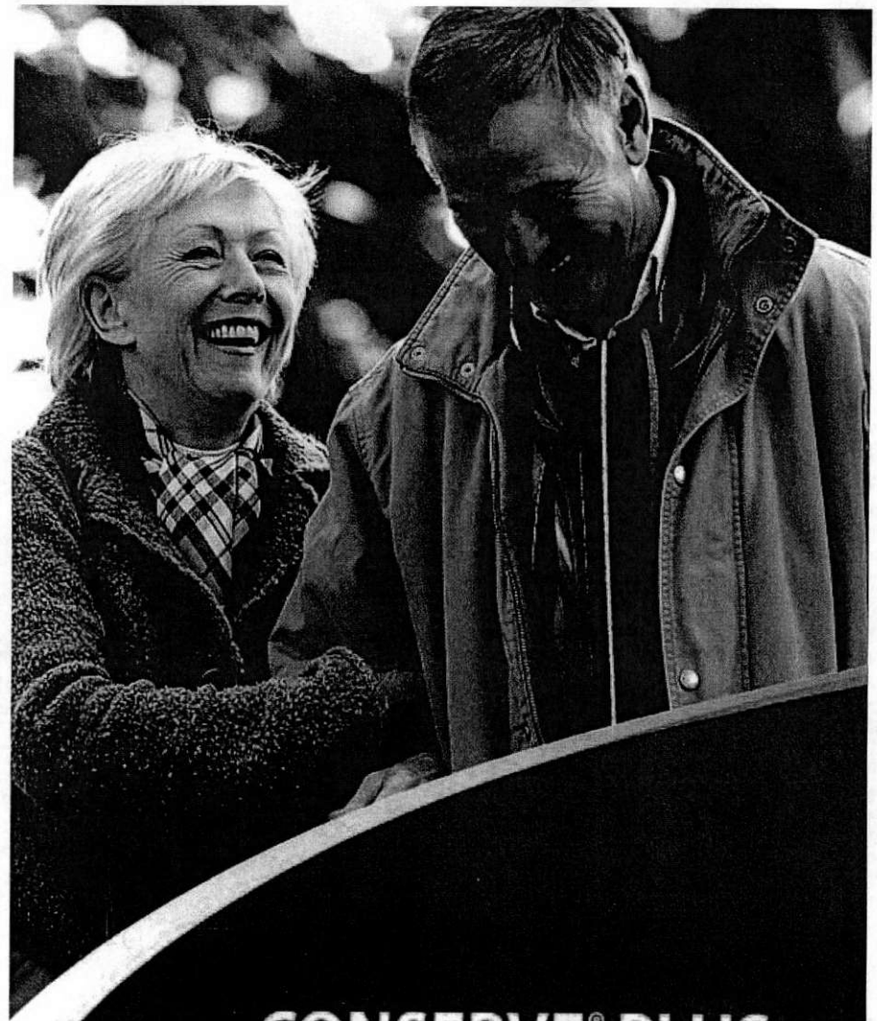
United States Patents
4,262,368; 4,301,553; 4,219,893; 4,467,801; 4,474,177; 4,721,104; 4,722,330; 4,759,767;

4,935,023; 5,002,545; 5,019,104; 5,035,699; 5,059,196; 5,098,436; 5,100,409; 5,415,662; 5,176,684; 5,275,603; 5,520,692; 5,431,656; 5,364,401; 4,298,992; 5,370,699; 4,718,413; 4,808,185

United Kingdom Patents
0120346; 0121142; 0243109; 0378294; 438918; 441059; 2,067,412

Australia Patents
595,265; 632,079; 627,269; 647,884; 647,885; 542,787; 606,747

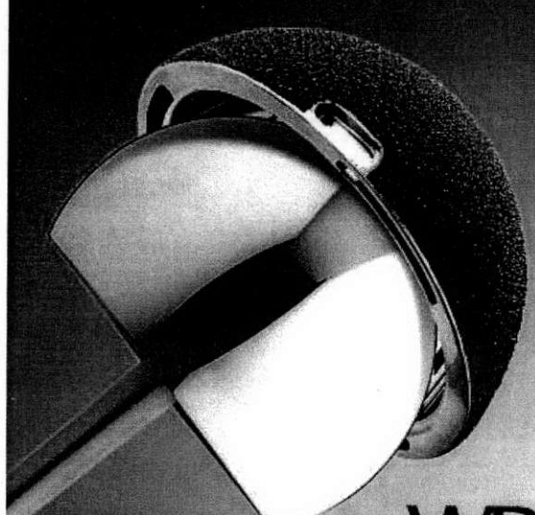
Additional patents pending.



CONSERVE® PLUS

Total Resurfacing Hip System

Patient Information



WRIGHT.

Table of Contents:

Glossary of Terms

Acetabular – *related to the hip socket*

Acetabulum *-hip socket*

Aseptic Lymphocyte Dominated Vasculitis Associated Lesion – *(ALVAL) Delayed chronic inflammatory response apparently due to metal sensitivity which may lead to revision of the implants*

Blood Urea Nitrogen – *(BUN) the amount of nitrogen in the blood in the form of urea. It is used to evaluate renal function.*

Calcification – *hardening of the tissue*

Colonoscopy – *test performed by a doctor to view the large intestine (colon) of a patient with a camera*

Congenital Hip Dysplasia – *dislocation of the hip at the time of birth due to abnormal development of one or all of the parts of the hip joint: the cup shaped socket in the hip bone; the ball of the thighbone; and the surrounding soft tissues*

Creatinine – *A chemical waste product that is generated from muscle metabolism. It is transported through the bloodstream to the kidneys where it is disposed of in the urine*

Cystoscopy – *test performed by a doctor to view the urethra and bladder of a patient with a camera*

Degenerative Joint Disease – *a condition that causes the loss of cartilage and bone in a joint that eventually leads to pain and loss of function*

Femoral – *related to the thighbone (femur)*

Femoral Neck Fracture – *breakage of the bone below the hip ball head*

Glomerular Filtration Rate – *(GFR) the flow rate of filtered fluid through the kidneys. It is used to evaluate renal function*

Hematoma – *clotted blood vessels that can form in a tissue, organ, or body space that is the result of a broken blood vessel; more commonly referred to as bruising and swelling*

Heterotopic Ossification –*deposits of bone in soft tissues around the hip joint. It usually does not affect how well the hip works, but it may decrease the range of motion at the hip. The condition needs surgery only if it causes pain or greatly limits motion*

Hip Dislocation – *a hip problem resulting from a separation of the ball from the socket in a hip replacement device*

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 resurfacing device*

Magnetic Resonance Imaging – *(MRI) is a medical imaging technique commonly used in radiology to visualize the internal structure and function of the body.*

Metal Ions – *particles from the hip device that are released into the body as the parts rub against each other*

Metallosis – *a bone infection that occurs around the metal hip resurfacing device due to material breakdown or patient sensitivity*

Migration *– a hip complication resulting from a movement of the device out of its original position*

Necrosis *– death of cells and living tissue caused by external factors, such as infection, toxins, or trauma*

Neurologic *– associated with the parts of central nervous system such as the brain, spinal cord, and nerves*

Osteoarthritis *– non-inflammatory degenerative disease of the joint characterized by degeneration of cartilage causing pain when the hip bones rub together*

Osteolysis *– a condition leading to the loss of bone after total joint replacement*

Osteomalacia *– softening of the bones*

Osteonecrosis *or* ***Avascular Necrosis*** *– a loss of blood supply to the hip bones characterized by changed shape and increased thickness of the bone, a flattening of the joint surface*

Osteoporosis *– a condition leading to bone loss that causes the bones to become brittle and weak*

Perforation *– a hole or break in the pelvic bone. Perforation occurs when erosion, infection, or other factors create a weak spot in the bone of the pelvis*

Pseudotumor *– an enlargement that resembles a tumor, resulting from inflammation, fluid accumulation, or other causes*

Rehabilitation *– doctor prescribed exercises that help improve hip movement*

Revision Surgery *– replacement of a resurfacing hip device with a new total hip device. Revisions can be required due to several reasons such as bone fracture, dislocation, infection, or migration of any device component*

Rheumatoid Arthritis *–chronic inflammatory disease that results in joint pain, stiffness and swelling. The disease process leads to severe and, at times, rapid deterioration of multiple joints, resulting in severe pain and loss of function*

Sigmoidoscopy *– test performed by a doctor to view the lower large intestine (lower colon) of a patient with a camera*

Subluxation *– partial dislocation of a joint*

Traumatic Arthritis *– swelling, redness, and pain in a joint resulting from an injury and identified by breakdown of the bone and soft tissue, bleeding in the joint space, increased thickness of the bone, a flattening of the joint surface, joint soft tissue separation from the underlying bone, and breakdown of the bone*

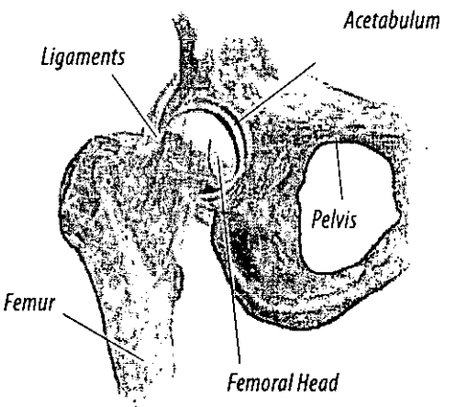
Traumatic Wound *– an injury caused by something outside the body*

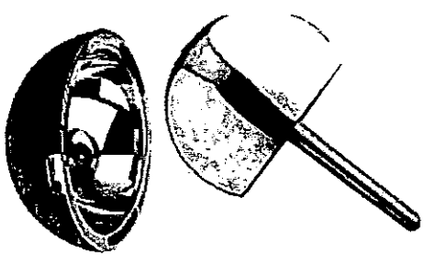
Trochanteric Bursitis *–swelling of the large sacs that separate the hip bones from the muscles and tendons of the thighs and buttocks. This results in tenderness on the upper, outside portion of the thigh bone*

Urinary Catheterization *–the insertion of tubing (catheter) into the bladder to aid in the emptying of urine from the bladder*

What is the CONSERVE® Plus Total Resurfacing Hip System?

The CONSERVE® Plus Total Resurfacing Hip System is composed of the following parts: the CONSERVE® Plus Acetabular Shell and the CONSERVE® Plus Femoral Component. Both parts are available in many different sizes.





CONSERVE® PLUS Acetabular Shell

CONSERVE® PLUS Femoral Component

CONSERVE® Plus Femoral Component: *The femoral component replaces a portion of the ball-shaped bone at the top of your thigh (femoral head) and has a small stem that is inserted into the top of your thighbone (femur). The femoral component is attached to your thighbone (femur) with bone cement.*

CONSERVE® Plus Acetabular Shell: *The shell replaces the damaged surface of your hip socket (acetabulum) and is attached initially by an interference fit (press-fit) and over time by tissue and/or bone growth (biological fixation) into the shell's outer porous coating.*

The femoral component moves within the cup. The surfaces that rub against each other are made from highly polished metal. This type of hip device is called a metal-on-metal hip resurfacing device.

What is the purpose of the CONSERVE® Plus Total Resurfacing Hip System? (Indications for use)

The CONSERVE® Plus Total Resurfacing Hip System relieves hip pain and improves hip function by replacing the parts of your hip that have been severely damaged by degenerative joint diseases. These diseases include: osteoarthritis, rheumatoid arthritis, traumatic arthritis, dysplasia, and avascular necrosis.

The CONSERVE® Plus Total Resurfacing Hip System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip replacement due to an increased possibility of requiring future hip joint revision.

When should the CONSERVE® Plus device not be used? (Contraindications)

You should not receive the CONSERVE® Plus Total Resurfacing Hip device if:

- You have an infection of the body or blood.
- Your bones are not yet fully grown.
- Your bones are not strong enough or healthy enough because:
  - o You have severe bone loss (osteoporosis) or have a family history of severe bone loss,
  - o You have bone loss (such as avascular necrosis) affecting more than half of your femoral head,
  - o You have multiple fluid-filled cavities (cysts) greater than 1 centimeter in your femoral head,
  - o A test (such as DEXA scan) may be needed to determine your level of bone loss.
- You have any blood vessel-related disease, muscle-related disease, or nerve- and muscle-related disease that may prevent the artificial hip joint device from remaining stable or that may prevent you from following instructions during the recovery period.
- You are a female of child-bearing age. It is unknown whether metal ions released by the device could harm an unborn child.
- Your kidneys are not working very well (function is significantly impaired). You will need testing (creatinine, GFR, BUN) before and/or after surgery to test your kidneys.

- You have a suppressed immune system due to diseases, such as AIDS, or are receiving high doses of corticosteroids.
- You are severely overweight.
- If you have had reactions to wearing metal jewelry, you may have what is called "metal sensitivity".

Your doctor will need complete information about your overall health to determine whether the CONSERVE® Plus Total Resurfacing Hip System is right for you. 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 your kidney or bone strength in the future.

What are some of the potential benefits of the CONSERVE® Plus device?

Your surgeon has decided that you will benefit from hip replacement surgery. The benefits may include the relief of pain and return of function of the hip. When thinking about the benefits of the CONSERVE® Plus Total Resurfacing Hip System, you should compare the possible risks and benefits of the CONSERVE® Plus Total Resurfacing Hip System to the risks and benefits of other types of artificial hip replacement devices:

Hip resurfacing versus a total hip replacement:

The CONSERVE® Plus Total Resurfacing Hip System is a hip resurfacing device. With a hip resurfacing device, the surgeon covers your hip socket with a metal cup, and covers your femoral head with a metal cap. (See Page 3) With a total hip replacement device, the surgeon covers your hip socket with a cup and replaces your femoral head with a metal ball attached to a long metal stem. The metal stem is inserted into your thighbone.

CONSERVE® Plus Total Hip Replacement

Traditional Total Hip Replacement

Metal-on-metal versus metal-on-plastic or ceramic-on-ceramic:

With metal-on-metal systems, the cap (ball) and the socket components are made from highly polished metal. The

CONSERVE® Plus Total Resurfacing Hip System is a metal-on-metal system. Other hip systems can have a metal ball with a plastic lined socket (metal-on-plastic) or a ceramic ball with a ceramic lined socket (ceramic-on-ceramic).

Each of the device types discussed above can significantly improve hip pain and function. However, specific potential benefits of the CONSERVE® Plus Total Resurfacing Hip System include:

- The CONSERVE® Plus Total Resurfacing Hip System's metal cup will not chip or crack as ceramic components can.
- The CONSERVE® Plus Total Resurfacing Hip System does not cause thighbone (femoral shaft) fractures as total hip replacement systems can.
- The CONSERVE® Plus Total Resurfacing Hip System may make future revision surgery easier, should that be required, because hip resurfacing surgery leaves your femoral head in place and there is no large metal stem placed in the thighbone. In contrast, revision surgery of a total hip replacement where your femoral head has been removed and a large stem is in place can be a more difficult operation.
- Dislocation of the ball head from the socket is less common with the CONSERVE® Plus Total Resurfacing Hip System than with total hip replacement devices. In the clinical study 1.3% of 292 patients treated with the CONSERVE® Plus Total Resurfacing Hip System experienced hip dislocation while the study ceramic-on-ceramic and metal-on-metal total hip replacement devices had a dislocation rate of 1.5% and 3.1%, respectively. There have been no revisions or removals related to dislocation of the CONSERVE® Plus Total Resurfacing Hip System.

What are some of the potential risks of the CONSERVE® Plus device?

The risks and complications associated with the CONSERVE® Plus Total Resurfacing Hip System are expected to be similar to those of other resurfacing and/or hip replacements.

The risks and complications include:

- Excessive bleeding
- Damage of blood vessels may occur due to surgery
- Delayed wound healing
- Sudden drop in blood pressure during surgery due to the use of bone cement or anesthesia
- Temporary or permanent nerve damage
- Allergic reaction due to anesthesia, medication, or device material
  - Allergic reaction to the implant's materials. As the parts rub against each other, metal ions are released into the body, which may cause an allergy. There are no known medical consequences of these ions at this time, however, studies are ongoing
- Infection, which can lead to removal of the device
- The femoral neck may break
- Device loosening from the surrounding bone
- Increase in hip pain and/or reduced function
- Hardening of the tissue (calcifications) or bony points around the devices
- Device related noise such as, clicking, popping, squeaking or grinding
- Ball and socket may separate (hip dislocation)
- Overuse of the device from too much weight or activity may cause the device to fail prematurely
- Change in the length of the treated leg (limb length discrepancy)
- Premature wear or breakage of the implant
- Bone breakage due to osteoporosis or accidents (trauma)
- Damage to the bones and tissue (tissue necrosis, pseudotumor) near the hip joint, including loss of the surrounding bone (osteolysis) or staining of the hip joint fluid (metalosis) due to wearing of the metal parts over time
- Pseudotumor; and
- Chronic inflammatory response due to metal sensitivity (Aseptic Lymphocyte Dominant Vasculitis Associated Lesion – ALVAL).

These potential adverse events may require additional medical and/or surgical procedures and should be discussed with your surgeon. Rarely these complications can lead to death.

What do the Clinical Studies Show?

A clinical study was performed to evaluate the safety and effectiveness of the CONSERVE® Plus Total Resurfacing Hip System. Clinical trial data was collected on 1366 hips implanted with the CONSERVE® Plus Total Resurfacing Hip System. Complication (safety) information was collected from this group of 1366 study procedures and, of these, 540 of 680 unilateral, original shell, cases comprised the 24-month safety group. Effectiveness information was collected from the 292 procedures in the Pivotal Unilateral Efficacy Cohort (original shell) and, of these, 264 were rated for pain and function (Harris Hip Score) at 24+ months after surgery.

Safety Data

Complication (safety) information was collected from the entire group of 1366 study procedures and, of these, 540 of 680 unilateral, original shell cases completed the 24-month safety data collection process.

Some complications occurred at a higher rate in CONSERVE® Plus patients versus other hip replacement systems. These complications were:

- Bone formation in surrounding tissue (heterotopic ossification)
- Bruising and swelling (hematoma)
- Infection
- Nerve problem
- Pain
- Wound problems
- Tenderness on the upper, outside portion of the thighbone (trochanteric bursitis)

However, the overall complication rate and types of complications were similar to the types reported for other hip replacement systems. The revision rate between CONSERVE® Plus patients and other hip replacement systems was also similar. 36 of 540 (6.7%) CONSERVE® Plus patients required revision surgery. Reasons for revision

in these 36 patients were: fracture of the neck of the thigh bone (19), loosening of the implant (6), infection (4), impingement of the implant (2), migration of the implant (1), protrusion of the implant into the wall of the pelvis bone (1), pain (1), and other reasons (2). There were no deaths directly related to the use of the device in the study.

Effectiveness Data

Effectiveness information was collected from the 292 procedures in the Pivotal Unilateral Efficacy Cohort (original shell) and, of these, 264 were rated for pain and function (Harris Hip Score) at 24+ months after surgery. Harris Hip Total scores were summarized in categories used to summarize clinical outcome. This scoring system is used to tell doctors how well patients are functioning with their hip replacement including their ability to walk (with or without a walking aid), and the patient's level of pain. Refer to Table 1.

Table 1

Harris Hip Total Score Category[1]	24+ Months		
	n	%	
Category			
90 -100 (Excellent)	227	86.0%	93.6%
80-89 (Good)	20	7.6%	
70-79 (Fair)	6	2.3%	
<70 (Poor)	11	4.2%	
Total	264		

Notes: [1] Post-op Harris Hip Total scores include procedures with zeros imputed for missing ROM and/or deformity.

What can you do before your surgery?

Your doctor may want you to meet the Physical Therapist (PT) even before the 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, here are a few simple ideas:

Rearrange 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.

Buy a firm pillow:

Putting a firm pillow on a low chair or sofa before sitting down may help reduce discomfort.

Remove electrical cords:

Remove, hide, or tape the electrical cords to the floor to avoid tripping over them.

Have an armchair available:

During rehabilitation, you may be told to only sit in armchairs as you will need the arms to help you sit down and get up.

Elevated toilet seat:

Arrange to have an elevated toilet seat and / or support bars fitted in your bathroom.

Pack up the throw rugs:

Rugs can shift or bunch, causing you to slip or trip. Don't take chances - remove them before your surgery.

Stock up on food:

It's a good idea to stock up on canned or frozen foods. To avoid bending over or using a stool or stepladder, store all supplies between waist and shoulder level for easy access.

Prepare a bed downstairs:

If your bedroom is upstairs or in the basement, prepare a bed on the ground floor of your home to use temporarily upon your return from the hospital.

Get help with household chores:

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 with these essential tasks, your healthcare team can assist you in making arrangements (in advance) for someone to help you around the home. As an alternative, you can also arrange a short stay at an extended care rehab facility while you recover.

In addition to preparing your home, it is important to be as "fit" and strong as possible before undergoing the CONSERVE® Plus Total Resurfacing Hip procedure. Strengthening the muscles around your hip and in your legs and arms will help to make recovery progress faster. Talk with your doctor or PT about exercises you can do to prepare for your surgery.

Also make sure there are no active infections within your body and stop smoking.

How is hip resurfacing performed?

The CONSERVE® Plus Total Resurfacing Hip System is similar to a total hip replacement from a surgical perspective.

- Instead of cutting off the arthritic femoral head (top of the thighbone), the head is reshaped and resurfaced with a metal mushroom-shaped cap.
- In the operating room, EKG electrodes will be placed on your chest and side to monitor your heart rhythm during surgery.
- The anesthesiologist will then inject medication through your IV line to put you to sleep (general anesthesia) or block feeling from the waist down (spinal anesthesia).
- Your surgeon makes an incision and exposes the hip joint.
- The hip socket is prepared in a similar fashion to a total hip replacement.
- The diseased cartilage is removed and a CONSERVE® Plus Acetabular shell is put (press fit) into place.
- In a similar manner, the diseased part of the femur (thighbone) is removed and the CONSERVE® Plus Femoral component is cemented in place.

The CONSERVE® Plus Femoral and Acetabular Shell components resurface both moving parts of the hip joint. All components of the CONSERVE® Plus Total Resurfacing Hip System are made of standard materials that have a long history of use in the human body.

The surgery itself generally takes between 1 to 1 ½ hours.

What can you expect after your operation?

Recovery from any operation varies from patient to patient and post-operative rehabilitation programs vary from hospital to hospital and surgeon to surgeon.

After surgery, you will need to rest your hip to allow proper healing. Your activity will be restricted during this healing period. During the first few weeks after surgery, you may be advised to put a pillow between your legs when turning over in bed, wear elastic stockings, use a raised toilet seat, take showers instead of baths, restrict activities such as sudden twisting or turning, crossing legs, and driving. Also, avoid exposing the scar to sunlight for the first 6 months; if the scar is exposed to the sun, sunscreen (SPF 30-45) is recommended.

Follow your surgeon's instructions carefully. Your surgeon will give you detailed post-operative instructions before you leave the hospital.

Even after the healing period, excessive loads placed on the implant through sudden trauma or high impact activities, such as running and jumping, can damage the joint.

Most hip replacement patients stay in the hospital three to five days;

- The length of your hospital stay will depend on your medical condition and your progress in rehabilitation
- Your surgeon will decide how much weight you will be able to put on the affected leg and will tell you how active you can be
- Until your surgeon says to walk on the hip, you must have someone or something (walker) to help aid walking to and from the toilet or other activities; too much motion of the hip may be harmful to the healing process
- If you are involved in heavy walking, running, lifting, or muscle strain activities, these heavy forces on your body may cause failure of the fixation, the device or both
- You should not expect the new hip device to restore function to the level of normal healthy bone
- You will have to visit your surgeon at various times after surgery to check hip pain and function
- You will have to go for X-rays on a regular basis to detect problems; the X-rays will also check the position of the hip implant and to check the surrounding bones.

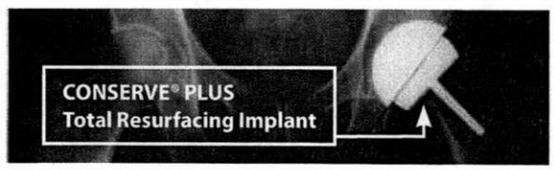
It is important to follow your surgeon's instructions carefully so healing from surgery can occur as quickly as possible.

Follow-up office visits may include physical therapy, radiologic exams, blood work, and urine analysis

What problems may occur during surgery, shortly after surgery, or later on?

What complications can happen during or shortly after surgery?

- Pain
- Femoral or acetabular (related to the hip socket) perforation (hole) or broken bones
- Broken bone while seating or implanting the device
- Damage to blood vessels
- Temporary or permanent nerve damage resulting in pain or numbness of the affected limb
- Undesirable shortening or lengthening of the limb caused by improper selection of the implant size
- Traumatic wounds of the hip from positioning of the leg during surgery
- Cardiovascular disorders including blood clots in the veins or lungs, or heart attack
- Pocket of blood caused by bleeding from a broken blood vessel which appears "black and blue"
- Delayed wound healing
- Infection



What complications can happen later on?

- Pain
- Broken bone by trauma or excessive loading (weight or force), particularly in the presence of poor bone quality
- A small piece of the thigh bone may pull away as a result of excess muscular tension, early weight bearing, or accidental weakening during surgery
- The thigh bone may not heal properly due to weak reattachment and/or early weight bearing
- Problems with either leg because of differences in leg lengths or because of lack of muscle
- Calcium deposits around the joint or bone formation, with or without ability to move the joint
- Inadequate range of motion due to improper selection or positioning of hip parts
- Device related noise such as, clicking, popping, squeaking or grinding
- Wear of metal moving surfaces may result in increased levels of cobalt and chromium metal particles in the body.

Effects and duration of increased metal ion concentrations are not known.

What are some symptoms that would prompt a call to your surgeon after your operation?

- Redness, swelling, or drainage from around the 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 turning of the leg; or
- Any sudden swelling in the thigh or calf. It will always be important to protect this new part of your body from infection.

WARNING: Always follow your surgeon's directions for activity limitations. Failure to do so may result in damage to your joint and may lead to device failure.

WARNING: Device failure may require additional surgery to remove the device (revision surgery).

WARNING: You should call your surgeon if your hip feels unsteady.

Options you will have if the device needs to be revised

If your CONSERVE® Plus Total Resurfacing Hip System components need to be revised sometime in the future, the CONSERVE® Plus Total Resurfacing Hip System may make future revision surgery easier because hip resurfacing surgery leaves your femoral head in place. The revision surgery would be a total hip replacement which uses a large metal stem placed in the thighbone instead of the small mushroom shaped femoral component.

What are some warnings or precautions that you should know about after your operation?

If you ever have any of the following procedures, you will need antibiotics before them to help protect the joint from the possibility of infection:

- Endoscopy of any kind, which includes: cystoscopy, colonoscopy, sigmoidoscopy and bronchoscopy
- Dental work, including teeth cleaning
- Surgery of any kind
- Urinary catheterization

If you have infection in any part of your body, contact your physician.

If a physician prescribes an MRI scan for you, inform the physician that the CONSERVE® Plus Total Resurfacing Hip System has not been evaluated for safety and compatibility in the MR environment. The CONSERVE® Plus Total Resurfacing Hip System has not been tested for heating or migration in the MR environment.

What can you do to improve your recovery?

The majority of your therapy and rehabilitation will occur once you have checked out of the hospital.

Your Physical Therapist (PT) will design an exercise program to increase the motion and strength of your hip and will teach you the exercises, making sure you know proper form before you begin. Your commitment to the physical therapy program will help your post-operative recovery.

Before you go home, a PT will teach you to climb stairs and transfer from a bed, chair, and car. Your PT may also give you a list of exercises to be performed at home every day. The objective is to become as independent as possible in your personal care and daily activities before you return home.

Take care to protect your joint replacement from unreasonable stresses and to follow your treating physician's instructions regarding activity level. Avoid high impact activities such as running and jumping, particularly during the first post-operative year while the bone is healing. Excessive force on the implant can lead to device failure (breakage or loosening). Artificial joint replacement devices can wear over time and may require replacement.

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

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. All implants have a limited expected service life and may need to be replaced at some time in the future.

Are there instructions for when you travel?

After you receive a metal implant, it may activate metal detector alarms. Tell the security officer about your artificial hip when you must pass through metal detectors in airports, stores, and public buildings. Ask your surgeon for a card that shows that you have had a hip replacement and if you should go through the metal detector system.

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 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 joint fusion. Additionally, your doctor can recommend non surgical therapy such as weight loss, mild exercise programs, physical therapy, assistive devices (such as canes), and lifestyle modifications.

Hip resurfacing versus a total hip replacement:

With a hip resurfacing device, the surgeon covers your hip socket with a metal cup and covers your femoral head with a metal cap. (See section 1) The CONSERVE® Plus Total Resurfacing Hip System is a hip resurfacing device. With a total hip replacement device, the surgeon covers your hip socket with a cup and replaces your femoral head with a metal ball attached to a long metal stem. The metal stem is inserted into your thighbone.

CONSERVE® Plus Total Resurfacing Hip System

Traditional Total Hip Replacement

Metal-on-metal versus metal-on-plastic or ceramic-on-ceramic:

With metal-on-metal systems, the cap (ball) and the socket components are made from highly polished metal. The CONSERVE® Plus Total Resurfacing Hip System is a metal-on-metal system. Other hip systems can have a metal ball with a plastic lined socket (metal-on-plastic) or a ceramic ball with a ceramic lined socket (ceramic-on-ceramic)

Metal-on-Metal

Ceramic-on-Ceramic

Metal-on-Poly

For Additional Information

You can ask your orthopaedic surgeon about total hip resurfacing, or visit **www.wmt.com** for more information.

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Arlington, TN 38002
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800.238.7188 toll-free
www.wmt.com

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1186 DM Amsterdam
The Netherlands
011.31.20.545.0100
www.wmt-emea.com

MH206-607

Patient: _____

Surgeon: _____

Date of Surgery: _____

Implant: _____

REF: _____

LOT #: _____

Facility: _____

- This patient has undergone joint replacement surgery utilizing an implant manufactured by Wright Medical Technology, Inc. The materials used for this implant may activate metal detection devices.
- Inform you doctor that you have an implant prior to dental work, surgery, endoscopy of any kind, urinary catheterization, or MRI scan.

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