

GENERAL INFORMATION

IMPORTANT Please read carefully before using this product.

The surgeon must be fully conversant with the applicable operative technique and/or instructions for use where available. If additional information concerning the operative technique is required the information should be requested from the applicable Corin Group Sales Department or distributor. The surgeon or the surgical team must inspect the implants, surgical instruments and single use disposable devices prior to surgery to ensure they are undamaged and appropriate for use in the surgical procedure.

The Cormet Hip Resurfacing System is a metal-on-metal hip resurfacing system. The system consists of a stemmed resurfacing femoral head component designed for cemented fixation and an acetabular component designed for cementless fixation. The acetabular component has a bi-coating™ of plasma sprayed titanium and hydroxyapatite (HA).

Materials

Table 1: Materials

Component	Material	Standard
Femoral Resurfacing Head	Cobalt Chromium Alloy	ASTM F75
Acetabular Component	Cobalt Chromium Alloy	ASTM F75
	Unalloyed Pure Titanium (coating)	ISO 5832 Part 2
	Hydroxyapatite powder (coating)	ASTM F1185

Sizing and System Compatibility

Each femoral head component is compatible with two acetabular components with the exception of the 56mm diameter head, which is only compatible with the 62mm nominal outside diameter (OD) acetabular cup.

Table 2: Description of Components

Femoral Head (Nominal Outside Diameter)	Acetabular Component (Nominal Inside Diameter of cup x Nominal Outside Diameter of cup)
40mm	40 x 46mm, 40 x 48mm
44mm	44 x 50mm, 44 x 52mm
48mm	48 x 54mm, 48 x 56mm
52mm	52 x 58mm, 52 x 60mm
56mm	56 x 62mm

Indications for Use

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

- 1 non-inflammatory degenerative arthritis such as osteoarthritis and avascular necrosis;
- 2 inflammatory arthritis such as rheumatoid arthritis.

The Cormet Hip Resurfacing 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 ipsilateral hip joint revision.

Contraindications

1. Patients with active or suspected infection in or around the hip joint;
2. Patients who are skeletally immature;
3. Patients with bone stock inadequate to support the device including:
 - Patients with severe osteopenia should not receive the Cormet Hip Resurfacing System 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 Cormet Hip Resurfacing device;
 - Patients with multiple cysts of the femoral head (>1cm) should not receive a Cormet Hip Resurfacing device;
 - Note – In cases of questionable bone stock, a DEXA scan may be necessary to assess inadequate bone stock.
4. Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery;
5. Females of child bearing age due to unknown effects on the fetus of metal ion release.
6. Patients with known moderate or severe renal insufficiency;
7. Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids;
8. Patients who are severely overweight;
9. Patients with known or suspected metal sensitivity (e.g., jewelry).

Warnings and Precautions

1. Patients on medications (such as high-dose or chronic amino glycoside treatment) or 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.
2. Currently, Corin does not have a commercially available modular femoral head for use with the Cormet resurfacing shell. If the Cormet resurfacing head must be revised to a total hip arthroplasty, the acetabular shell should also be revised even if it is well fixed.
3. Based on an analysis of a multicenter prospective study of 1030 patients in 14 centers the following were identified as risk factors for revision: Patients who are female, who receive a smaller component size (40 or 44mm), who have a diagnosis other than osteoarthritis (i.e., avascular necrosis, rheumatoid arthritis), a leg length discrepancy greater than or equal to 1 cm, or low baseline HHS have a greater risk of revision than other patients. The more risk factors a patient has, the greater the risk of procedure failure requiring a revision to the hip. Please see Tables 17 and 19 for revision rates for each risk factor group.
4. 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 Cormet Hip Resurfacing System should use this device. Contact Corin USA or Stryker Orthopaedics for the surgical technique manual and procedural training protocol.

5. Appropriate selection, placement and fixation of the resurfacing hip components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.

Preoperative

1. Corin Group provides written operative techniques to ensure that the surgeon and the surgical team are fully versed with the operative procedure.
2. If, during pre-operative planning, an appropriately sized component is not available the procedure should not take place. An appropriate size range of implants should be available prior to performing the surgical procedure.
3. Do not scratch the femoral or acetabular components' articulating surfaces
4. Do not use any component of the Cormet Hip Resurfacing System with another manufacturer's implant components, because designs and tolerances may be incompatible and can lead to device failure.
5. Previous hip surgery such as osteotomy, core decompression, hemiresurfacing, or internal fixation may increase the risk of early failure.
6. 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.
7. Radiographic templates are available to assist in the preoperative prediction of component size and style.

Intraoperative

1. Use the recommended instruments and the recommended surgical technique.
2. Using instruments other than the associated Cormet Hip Resurfacing instruments may result in inaccurate placement.
3. Avoid notching the femoral neck, as this may lead to femoral neck fracture.
4. 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.
5. 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.
6. The trial prostheses should not be implanted.
7. Inspect the packaging of ALL sterile products for flaws before opening. Assume the product is not sterile in the presence of any flaws.
8. Discard ALL nonsterile or contaminated products.
9. Do not contour or bend an implant as it may compromise its fatigue strength and cause failure under load.
10. Do not re-use an implant. All implants are intended for single-use only.
11. Improper selection, placement, positioning and fixation of the implant components may result in early implant failure.

12. Malalignment of the components and/or soft tissue imbalance may cause excessive wear and early implant failure.
13. Avoid placing the femoral component in varus. Varus placement of femoral component has been associated with femoral neck fracture.
14. Avoid overly abducting the acetabular component, which can accelerate wear.
15. Ensure that the head outer diameter and acetabular inner diameter match prior to implanting.
16. The Corin operative techniques provide additional procedural information.

Hydroxyapatite-Coated Implants

1. Do NOT allow the HA-coated acetabular component to contact any substance other than the device packaging, clean gloves, or the patient's tissue.
2. Do NOT use cement with these HA-coated implants.
3. Take care to achieve a stable press fit. The HA-coated surface is not intended to compensate for inadequate implant fixation.

Postoperative

1. Excessive physical activity levels, excessive patient weight, and trauma to the joint replacement may cause early failure of the implant.
2. Loosening of the component may increase production of wear particles and accelerate damage to the bone, making successful revision surgery more difficult.
3. Routine postoperative follow-up is recommended to monitor implant position and patient well-being over time.

Patient Education

1. Warn the patient of the surgical risks, possible adverse effects and possible operative complications that may occur with joint arthroplasty.
2. Warn the patient of the limitations of artificial joint replacement devices.
3. 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.
4. Warn the patient that artificial joint replacement devices can wear out over time, and may require replacement.
5. 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 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 Cormet Hip Resurfacing device related adverse events are:

- femoral neck fracture
- femoral component migration/loosening
- acetabular component migration/loosening
- femoral subsidence
- dislocation
- greater trochanter fracture
- lesser trochanter fracture

A complete list of the frequency and rate of complications and adverse events identified in the clinical study are provided in the Summary of Clinical Studies, Tables 12-14.

Potential Adverse Effects

The following adverse effects may occur in association with hip replacement surgery including the Cormet Hip Resurfacing System:

1. Device failure because the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
2. Dislocation of the hip resurfacing prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
3. Loosening of hip resurfacing components can occur. Early mechanical loosening may result from inadequate initial fixation, 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.
4. Fatigue fracture of the implants as a result of excessive loading, malalignment, or trauma.
5. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
6. Surgical complications including, but not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
7. A sudden, pronounced, intraoperative blood pressure decrease due to the use of bone cement.
8. Hematoma or damage to blood vessels resulting in large blood loss.
9. Delayed wound healing.
10. Superficial or deep infection. Infections may occur months to years after surgery and these infections are difficult to treat and may require reoperation with removal surgery and later replacement at another time.
11. Increased hip pain and/or reduced hip function.
12. Metal sensitivity reactions or allergic reactions or metallosis.
13. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb. Surgeons should advise patients of these potential adverse effects.
14. Bone perforation or fracture (occurring either intraoperatively or occurring postoperatively as a result of trauma, excessive loading, osteolysis or osteoporosis).
15. Wear deformation of the articular surface (as a result of excessive loading or implant malalignment).
16. Limb length discrepancy.
17. Osteolysis and/or other periprosthetic bone loss.

Any of these adverse effects may require medical or surgical intervention. Rarely, these adverse effects may lead to death.

Summary of Clinical Study

Purpose of the Investigation

The purpose of this investigation was to test the hypothesis that the Cormet Hip Resurfacing System is as effective as conventional total hip arthroplasty. The Cormet Hip Resurfacing System was the investigational treatment and a conventional total hip arthroplasty system served as the control group. Effectiveness was measured via a composite endpoint to be described below. Safety was determined by collection of the incidence of perioperative and postoperative complications.

Study Design

A prospective, multi-center, IDE study was conducted utilizing components of the Cormet Hip Resurfacing System in the United States.

The control group was comprised of total hip arthroplasty patients with an alumina ceramic total hip system. These ceramic total hip prostheses were approved via PMA. Table 3 compares the investigational and study parameters.

Table 3 – Protocol Comparisons

Protocol Element	Cormet IDE Study	Ceramic Total Hip (Control)
Type of Study	IDE – Hip Resurfacing	IDE – Total Hip Arthroplasty
Bearing Type	Metal-on-Metal	Ceramic-on-Ceramic
Study Design	Prospective, non-randomized, historical control	Prospective, randomized
Number of centers	14	16
Dates of enrollment	5/17/2001- 8/5/2003 (pivotal) Continued access through July 2006 (ongoing)	10/29/1996 – 10/20/1998
Number of procedures	1148	349
Follow-Up Intervals	Preoperative, 6 weeks, 6, 12, 24 and 24+ months*	Preoperative, 6 weeks, 6, 12, 24 and 24+ months*
Outcome Measures	Harris Hip Score Adverse Events Radiographs Questionnaire	Harris Hip Score Adverse Events Radiographs Questionnaire

* 24+ month evaluations include all 24 month evaluations completed, as well as data from a later visit, if the 24 month evaluation was not available.

The patient populations recruited into both studies were similar. A side-by-side comparison of the inclusion/exclusion criteria between the studies is presented in Table 4.

Table 4: Inclusion/Exclusion Comparison

	Inclusion/Exclusion	Cormet Approved Protocol	Control Group Study
Well matched	Is skeletally mature	X	X
	Is mentally capable of follow-up	X	X
	Will be available for 2-year follow-up	X	X
	Deemed candidate by diagnosis of investigator	X	X
	No active infection	X*	X
	No severe osteoporosis	X*	X
	Not a prisoner	X	X
	Is not pregnant	X	X
	Is not morbidly obese	X*	X*
	No ipsilateral previous surgery	X	X
Differences	No extensive deformity of femoral head	X*	Not relevant
	No known allergy to implants	X	None included in study
	No neoplastic disease	X*	None included in study
	No above the knee amputation either extremity	X	None included in study
No Effect	Has preoperative HHS <70 points	X	No limits
	No Congenital Dysplasia of the Hip (CDH)	X	Included in study
	Age	No limits	21-75 years
	Inflammatory arthritis	Included in study	X

*PI discretion

Composite Clinical Success Endpoints

A patient is defined as a Composite Clinical Success (CCS) if at 24 months all of the following criteria outlined in Table 5 are met.

Table 5: Summary of the Composite Clinical Success

Composite Clinical Success Criteria
Harris Hip Score ≥ 80 at Month 24+
No revisions/pending revisions
Radiographic Success Criteria
Acetabular Migration (vertical/horizontal): <5mm
Acetabular Migration (varus/valgus): <5°
Acetabular Radiolucencies: not in all zones
Femoral Subsidence (axis femoral canal) < 5mm or Femoral Tilt varus/valgus <1°
Femoral Radiolucencies: not in all zones
Absence of device related Adverse Events

Study Objectives and Assessments

Study Population

Corin collected US IDE clinical trial data on 1154 cases implanted with the Cormet Hip Resurfacing System. Six procedures involved use of a pegged acetabular component, not part of the IDE. These cases were analyzed separately. Study data were therefore presented on 1148 study cases. There were no major protocol deviations reported during a comparable timeframe in the control group, however, there was one approved deviation for inflammatory arthritis. These data are not included in this submission. Eight investigational procedures involved enrollment under the compassionate use provisions. The study populations are identified in Table 6.

Table 6: Study Cohort Definitions

Cohort Name	Definition	Procedures/patients
All Enrolled	All patients enrolled in either the pivotal study or continued access.	1148/1030
Pivotal Study Unilateral	Unilateral patients enrolled in the pivotal study. Includes patients who had second side replaced after two years of follow-up (730 days). This was the primary analysis cohort.	337/337
Pivotal Study Bilateral	Patients with first implant in the pivotal study who had their second hip replaced within 730 days of the index procedure. There were four incidences where the second hip was not included in this study group because of the use of pegged cups.	105/55
Continued Access	Patients implanted after the pivotal study closed (Aug 6, 2003) under the continued access provision. Note: seven of these patients are also included in the pivotal study bilateral patient population above.	698/640
Compassionate Use	Implanted with the investigational device under compassionate use between the end of the pivotal IDE study and the beginning of continued access approval.	8/7

Demographics

The demographics for the pivotal unilateral study as compared to the control and the demographics for all other populations are identified in Tables 7-8.

Table 7: Comparison of Pivotal Study to Control

Population	Investigational Pivotal Study Unilateral Patients	Ceramic Total Hip Control Pivotal Study Unilateral Patients	Wilcoxon (continuous) or Chi-squared (discrete) P values
Number of procedures	337	266	
Number of patients	337	266	
Mean Age	50.1	53.3	<0.01
Gender M/F	67.7%/32.3%	62%/38%	0.150
Mean weight (lbs)	190.4	188.7	0.692
Diagnosis	85.8% OA, 1.2% RA, 13.1% AVN	83.7% OA, 16.3% AVN	For Diagnosis=OA p=0.135
Preoperative HHS mean total score	50.1, SD=11.6	49.7, SD=11.3	0.233

Table 8: Demographics for Other Populations

Population	IDE Pivotal Study Bilateral	Continued Access	All Enrolled
Number of procedures	105	698	1148
Number of patients	55	640	1030
Mean Age	47.7	52.3	51.2
Gender M/F	71.4%/28.6%	74.2%/25.8%	71.9%/28.1%
Mean weight (lbs)	195.1	194.9	193.8
Diagnosis	81.0% OA, 1.9% RA, 17.1% AVN	92.1% OA, 0.3% RA 7.6% AVN	89.1% OA, 0.8% RA 10.1% AVN
Preoperative HHS mean total score	48.7, SD=11.8	50.1, SD=11.4	50.0, SD=11.5

Patient Accounting

Pivotal Study Unilateral Patient Accountability

The follow-up time points for both the investigational and control studies are included in Table 9.

Table 9: Follow-up Intervals Comparison

	Cornet Approved protocol	Cornet PMA submission	Ceramic Total Hip Control
6 weeks	±2 weeks	±2 weeks + expanded	±3 weeks
6 months	±1 month	±1 month + expanded	±1 month
1 year	±2 months	±2 months + expanded	±2 months
2 years	±2 months	±2 months + expanded	±2 months
2+ years		Any evaluation 22+ months=24+ months	

Table 10 presents an overview of the data available for the pivotal study cohort.

Table 10: Pivotal Study Unilateral Patient Accountability

Status at Month 24+	Number of Subjects
Pivotal study group enrollment	337
Patients with complete CCS score	292
Patient died before month 24+	1
Patients not evaluated for CCS	44
Died after 24 month interval	2
Complete HHS data only	9
Complete radiographic data only	5
Patients with no Month 24+ data; Potential lost to follow-up	28

The availability of follow-up evaluation for the investigational and control Pivotal Study Unilateral group is provided in Table 11.

Table 11: Procedure Accounting and Follow-up Compliance Table Pivotal Study Unilateral Patients and Controls

As of Date of Database Closure	Pre-Op		Week 6		Month 6		Month 12		Month 24		Month 24+		Month 36	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
(1) Theoretical follow-up	337	266	337	266	337	266	337	266	337	266	337	266	314	266
(2) Cumulative deaths including non-theoretically due	0	0	0	0	0	0	0	1	1	2	1	2	4	2
(3) Cumulative revisions including non-theoretically due	0	0	2	1	5	1	7	3	16	3	16	3	24	3
(4) - Not Yet Overdue	0	0	0	0	0	0	0	0	0	0	0	0	32	0
(5) - Deaths+revisions among theoretical due	0	0	2	1	5	1	7	4	17	5	17	5	26	5
(6) = Expected due for clinic visit	337	266	335	265	332	265	330	262	320	261	320	261	256	261
(7) = Expected due+revisions among theoretical due	337	266	337	266	337	266	337	265	336	264	336	264	280	264
All Evaluated Accounting (Actual^B) Among Expected Due Procedures¹														
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
(8) All Evaluated Visit Compliance (%)	100.0%	100.0%	99.1%	99.2%	90.4%	94.0%	89.7%	98.1%	85.6%	97.7%	91.3%	98.5%	39.8%	73.2%
(9) Harris Hip Total Score	337	252	328	245	288	238	285	245	263	246	283	252	77	186
(10) Radiographic evaluation			313		232		234		259		291		53	
(11) CCS at Mos. 24, 24+ or HHS+radio. Otherwise			332	245	297	238	294	245	243	250	292	256	97	186
(12) Actual ^B % Follow-up for CCS or HHS+radio.CCS			99.1%	92.5%	89.5%	89.8%	89.1%	93.5%	72.3%	94.7%	86.9%	97.0%	37.9%	71.3%
Within Window Accounting (Actual^A) Among Expected Due¹														
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
(13) Harris Hip Total Score	337	252	277	221	161	183	192	215	200	206	281	251	22	156
(14) Radiographic evaluation			277		161		192		202		283		22	
(15) CCS at Mos. 24, 24+ or HHS+radio otherwise			277	221	161	183	192	215	202	209	285	254	22	156
(16) Actual ^A % Follow-up for CCS or HHS+radio.CCS			82.7%	83.4%	48.5%	69.1%	58.2%	82.1%	60.1%	79.2%	84.8%	96.2%	8.6%	59.8%
¹ Actual A: Patients contributing all endpoint data that were evaluated within the protocol defined window. Actual B: Patients contributing any data that were evaluated at a visit regardless of whether the visit was within the follow-up windows (not overlapping other protocol defined visit intervals)														

Pivotal Study Unilateral

The follow-up rate at Month 24+ for patients with complete information to determine safety and effectiveness was 84.8% (285/336) for the investigational group and 96.2% (254/264) for the control group, as shown in Table 11.

The following follow-up rates are also of interest:

Pivotal Study Bilateral

At Month 24+, the follow-up rate is 56.1% (55/98) in comparison to 95% (79/83) for the bilateral control cohort.

Continued Access

At Month 24+, 54.9% (134/244) of subjects due for evaluation have complete Harris Hip Scores and 6.1% (15/244) subjects have complete radiographic data. Many subjects have not reached the Month 24 endpoint.

All Enrolled

At Month 24+, the follow-up rate is 50.7% (348/686) in comparison to 96.5% (335/347) for the control "all enrolled" cohort. In addition, although there have been 1,148 procedures completed to

date, many of the patients have not yet reached the Month 24+ endpoint in the continued access study.

Safety Data

The safety of the Cormet Hip Resurfacing System was evaluated on the basis of adverse events which were defined as any untoward medical occurrence during the course of the investigation including any unintended sign, symptom, or disease related to the device use.

Systemic

Systemic adverse events are defined to include all events not directly related to the operative procedure or the device. Refer to Table 12 for a list of systemic adverse events for all enrolled procedures.

Table 12: Systemic Adverse Events for All Enrolled Investigational and Control Devices

	Investigational			Control			Exact p-value ³
	n ¹	N ²	%	n ¹	N ²	%	
Systemic							
Arrhythmia (operative)	1	1148	0.1%	0	349	0.0%	1.000
Bronchopulmonary	2	1148	0.2%	12	349	3.4%	<0.001
Carcinoma	4	1148	0.3%	18	349	5.2%	<0.001
Cardiovascular	14	1148	1.2%	33	349	9.5%	<0.001
Death unrelated to device	6	1148	0.5%	5	349	1.4%	0.142
DVT	9	1148	0.8%	0	349	0.0%	0.128
Gastrointestinal	8	1148	0.7%	19	349	5.4%	<0.001
Genitourinary	8	1148	0.7%	20	349	5.7%	<0.001
Infection remote location	10	1148	0.9%	4	349	1.1%	0.750
Lack of nutrition	1	1148	0.1%	0	349	0.0%	1.000
Low hemoglobin/hematocrit	3	1148	0.3%	0	349	0.0%	1.000
Neuropathy	1	1148	0.1%	0	349	0.0%	1.000
Neurosensory	8	1148	0.7%	32	349	9.2%	<0.001
Nosebleed	1	1148	0.1%	0	349	0.0%	1.000
PE	4	1148	0.3%	1	349	0.3%	1.000
Rash	8	1148	0.7%	10	349	2.9%	0.003
Thrombophlebitis	0	1148	0.0%	3	349	0.9%	0.013
Trauma (non-hip related)	10	1148	0.9%	30	349	8.6%	<0.001
Varicose veins	1	1148	0.1%	0	349	0.0%	1.000
Other	218	1148	19.0%	102	349	29.2%	<0.001

¹ Number of procedures experiencing this type of complication

² Total population number, 24+ Month data only available on 532 procedures.

³ Two-sided Fisher's Exact tests. Comparisons were not performed for femoral neck notched (operative), greater trochanter notching (operative), ceramic insert chip (operative), and femoral neck fracture since both devices were not exposed to these types of events. Also, p-values are not reported when there were no events in either group.

Hip Related Events

Hip related events were the most reported postoperative complications concerning the hip or operative site. Hip related complications by time of occurrence are provided in Table 13.

Table 13: Hip Related Adverse Events by Time Occurrence All Enrolled Procedures

	Intra-operative		Post Surgery to Week 6		Week 6 To Month 6		Month 6 to Month 12		Month 12 to Month 24		Post Month 24		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Hip Related Events														
Acetabular crack (operative)	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Acetabular malpositioned (operative)	0	0	0	0	1	0	0	0	3	0	0	0	4	0
Broken drill bit	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Bursitis	0	0	0	0	14	5	10	4	5	4	4	3	33	16
Deep Infection	0	0	0	0	0	0	0	1	2	0	1	0	3	1
Elevated metal ion level	0	0	0	0	1	0	0	0	0	0	0	0	1	0
Femoral Crack (operative)	0	12	0	0	0	0	0	0	0	0	0	0	0	12
Femoral neck notched (operative)	6	0	0	0	0	0	0	0	0	0	0	0	6	0
Femoral radiolucency	0	0	0	0	0	0	1	0	6	0	5	0	12	0
Greater Trochanter Notching (operative)	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Hematoma	1	0	3	3	2	0	1	0	1	0	0	0	8	3
Heterotopic Bone Formation	0	0	2	6	4	5	0	0	7	1	0	1	13	13
Hip Pain (operative side)	0	1	15	2	17	3	10	1	12	1	7	1	61	9
Leg Length Discrepancy	1	0	7	0	8	0	1	0	3	0	2	0	22	0
Limp	0	0	7	0	5	0	1	0	0	0	0	0	13	0
Loose Body	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Muscle Weakness	2	0	2	0	5	1	0	0	1	0	0	0	10	1
Myositis ossificans	0	0	1	0	3	0	1	0	1	0	0	0	6	0
Nerve palsy	1	2	1	3	2	0	0	0	0	0	0	0	4	5
Skin split	1	0	0	0	0	0	0	0	0	0	0	0	1	0
Soft tissue trauma	0	0	1	0	0	2	0	2	0	6	1	4	2	14
Squeaking implant/clicking	0	0	2	0	10	0	4	0	4	1	0	1	20	2
Subchondral cyst	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Subluxation	0	0	1	0	1	0	1	0	0	0	3	0	6	0
Superficial infection	0	0	4	5	2	0	1	0	0	0	0	0	7	5
Tendonitis	0	0	1	1	7	1	3	3	6	1	3	0	20	6
Trochanteric Crack (operative)	0	7	0	0	0	0	0	0	0	0	0	0	0	7
Wound Related (non-infected)	0	0	17	16	1	0	2	1	2	0	0	0	22	17
Other	0	4	0	1	2	0	2	1	1	1	0	1	5	8

Device Related

A time course distribution of various device related complications between the investigational and control populations is presented in Table 14.

Table 14: Device Related Complications by Time Occurrence All Enrolled Procedures

	Intra-operative		Post Surgery to Week 6		Week 6 To Month 6		Month 6 to Month 12		Month 12 to Month 24		Post Month 24		Total	
	I	C	I	C	I	C	I	C	I	C	I	C	I	C
Device Related Events														
Acetabular Fracture	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Acetabular loosening	0	0	3	0	3	0	0	0	3	0	2	0	11	0
Avulsed lesser trochanter	0	0	0	1	0	0	1	0	0	0	0	0	1	1
Ceramic Insert Chip (operative)	0	8	0	0	0	0	0	0	0	0	0	0	0	8
Dislocation	0	0	1	8	0	2	0	0	1	0	0	0	2	10
Femoral Fracture (operative)	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Femoral Fracture (post-op)	0	0	0	4	0	2	0	0	0	0	0	1	0	7
Femoral loosening	0	0	0	0	0	0	1	0	7	0	6	0	14	0
Femoral neck fx	0	0	3	0	12	0	5	0	5	0	1	0	26	0
Femoral subsidence	0	0	0	0	1	0	1	1	1	1	1	0	4	2
Trochanter (greater) fx	0	0	0	0	0	0	0	0	0	0	1	0	1	0

Revisions

A revision is defined as an adverse event necessitating removal or replacement of the original surgical device. A revision is considered to be the most severe adverse event as it indicates total failure of the surgical procedure or device. Tables 15 and 16 identify the study cohort and reasons for revision and or removal of study components.

Table 15: Revisions in Pivotal Unilateral, Pivotal Bilateral, Continued Access, All Enrolled and Control Procedures

	Pivotal Unilateral (all procedures)	Pivotal Unilateral with Month 24+ Follow-up	Pivotal Bilateral (all procedures)	Continued Access* (all procedures)	Compassionate Use (all procedures)	All Enrolled (all procedures)	All Enrolled with Month 24+ Follow-up	Control All Enrolled with Month 24+ Follow-up
Revisions	24	24	4	16	0	44	44	5
N	337	302	105	698	8	1148	532	266
%	7.1%	7.9%	3.9%	2.3%	0.0%	3.8%	8.3%	1.9%

*Most continued access procedures have not been followed for 24+ Months.

Table 16: Reasons for Revision in Pivotal Unilateral, Pivotal Bilateral, Continued Access and All Enrolled Procedures

	Pivotal Study Unilateral	Pivotal Study Bilateral	Continued Access	Compassionate Use	Total
Number	337	105	698	8	1148
Femoral Neck Fracture	8	2	11	0	21
Acetabular Component Loosening	4	0	4	0	8
Femoral Component Loosening	11	0	0	0	11
Deep Joint Infection	0	1	1	0	2
Dislocation	1	0	0	0	1
Femoral Subsidence	0	1	0	0	1
Total	24	4	16	0	44

Considering the denominator of the entire pivotal group as 337 procedures, the revision rate is 7.1%. However, only 302 of the pivotal group procedures had Month 24+ follow-up available, making the revision rate for the pivotal unilateral group 7.9% (24/302). Considering all enrolled procedures, the revision rate is 8.3% (44/532) if only procedures with Month 24+ follow-up are taken into consideration.

Five patients (1.9%, 5/266) were reported to have a revision of one or more components of the ceramic total hip system in the All Enrolled control group at Month 24+ follow-up. The reasons for revision were femoral fracture, recurrent dislocation, deep joint infection, hip pain with suspected sepsis, and post traumatic femoral component subsidence and loosening.

Risk Factor Analysis

A post-hoc subgroup analysis (Table 17) showed that within this patient cohort certain patients were at greater risk of experiencing a revision. Males had a lower revision rate than females (6.5% vs. 12.9%). Patients in whom a smaller component was implanted (40 or 44mm), patients with a diagnosis other than Osteoarthritis (OA, i.e., Avascular Necrosis, Rheumatoid Arthritis), patients with significant leg length discrepancy (≥ 1 cm) and baseline HHS in the lowest quartile of function all had revision rates greater than the overall average of 7.9% for the Pivotal Unilateral group or 8.3% for the All Enrolled group with a Month 24+ follow-up.

Table 17: Risk of Revision in Pivotal Unilateral Cohort and All Enrolled Procedures

		Pivotal Unilateral (all procedures)	Pivotal Unilateral with Month 24+ Follow-up	All Enrolled (all procedures)	All Enrolled with Month 24+ Follow-up
Gender	Female	11.9% (13/109)	12.8% (13/102)	6.5% (21/323)	12.4% (21/170)
	Male	4.8% (11/228)	5.5% (11/200)	2.8% (28/825)	6.4% (23/362)
Small Component Size	40/44 mm	16.7% (13/178)	17.3% (13/75)	7.4% (22/296)	15.2% (22/145)
	>40/44 mm	4.3% (11/259)	4.9% (11/227)	2.6% (22/843)	5.7% (22/387)
Non Osteoarthritis Diagnosis	AVN	13.6% (6/44)	15.8% (6/38)	6.9% (8/116)	12.7% (8/63)
	RA	25.0% (1/4)	25.0% (1/4)	11.1% (1/9)	14.4% (1/7)
	Osteoarthritis	5.9% (17/289)	6.5% (17/260)	3.4% (35/1023)	7.6% (35/462)
Leg Length Discrepancy greater than or equal to 1 cm	≥ 1 cm	13.0% (12/92)	14.5% (12/83)	6.1% (18/296)	14.0% (18/129)
	<1 cm	4.9% (12/245)	5.5% (12/219)	3.1% (26/849)	6.5% (26/403)
Baseline lowest quartile of function (HHS)	< 42.58	17.7% (15/85)	20.3% (15/74)	6.4% (18/283)	13.1% (18/137)
	≥ 42.58	3.6% (9/252)	4.0% (9/228)	3.1% (26/846)	6.7% (26/391)
Among 1 st 25 procedures within a specific site	First 25	8.2% (12/147)	8.9% (12/135)	6.8% (16/234)	8.3% (16/192)
	After 1 st 25	6.3% (12/190)	7.2% (12/167)	3.1% (28/914)	8.2% (28/340)

As an additional post-hoc analysis, the initial twenty-five (25) procedures at each center were evaluated to determine whether a learning curve could explain the number of revisions noted in the study. However, evaluation of the procedures with adequate follow-up data did not reveal revision rates to be significantly affected by a learning curve. One site (Site 5) had a greater revision rate than the other surgical sites. Table 18 compares the types of patients who had surgery at Site 5. Site 5

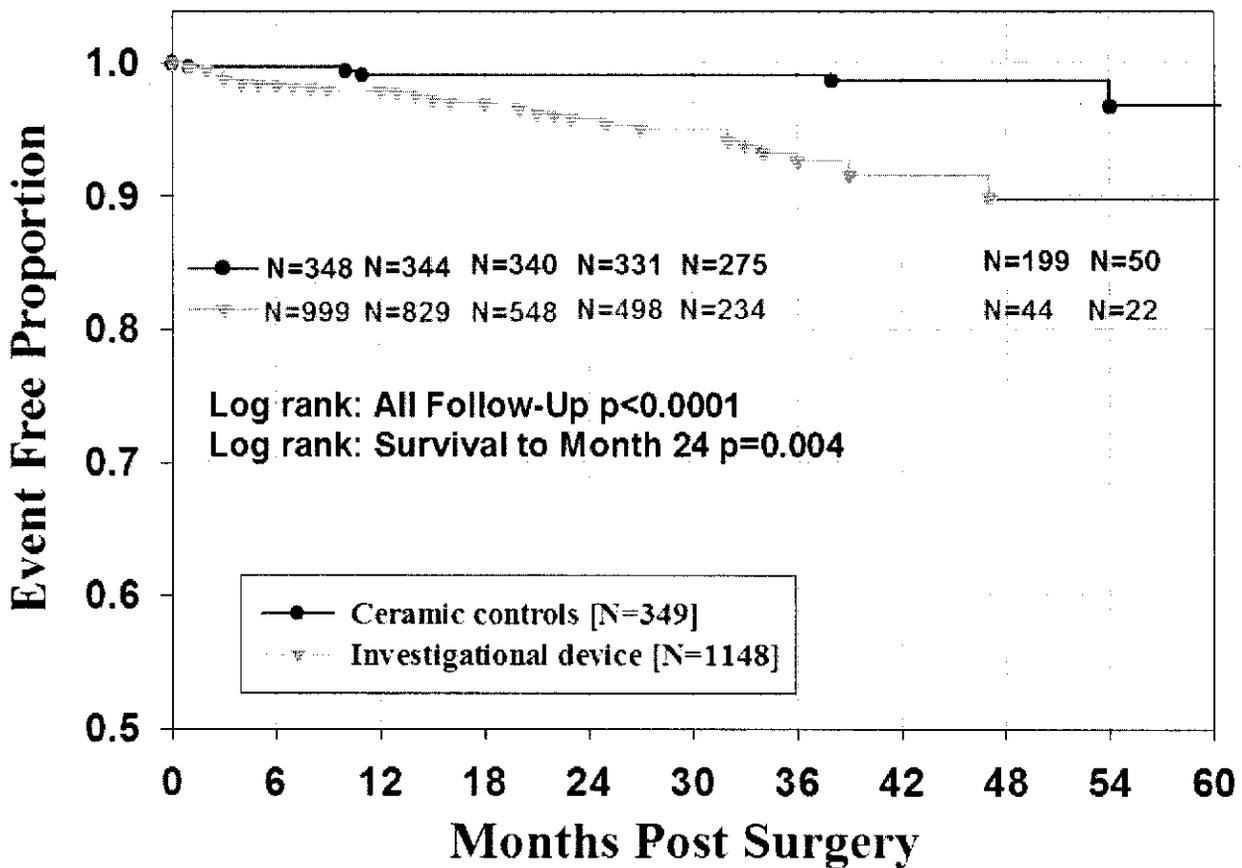
had a higher percentage of patients who required a small component size, had a greater leg length discrepancy, and the lowest function HHS scores. Site 5 also had a lower percentage of surgical patients with diagnosis other than osteoarthritis.

Table 18: Prevalence of Risk Factors for Pivotal Unilateral and All Enrolled Patients with and without excluding Site 5

		Pivotal Unilateral	Pivotal Unilateral Excluding Site 5	Pivotal Unilateral Site 5 Only	All Enrolled	All Enrolled Excluding Site 5	All Enrolled Site 5 Only
Small Component Size (40 or 44mm)	%	23.1%	22.7%	26.3%	26.0%	24.0%	35.6%
	n	78	68	10	296	227	69
	N	337	299	38	1139	945	194
Non Osteoarthritis Diagnosis	%	14.2%	15.7%	2.6%	10.9%	12.2%	4.6%
	n	48	47	1	125	116	9
	N	337	299	38	1148	954	194
Leg Length discrepancy ≥ 1cm	%	27.3%	19.7%	86.8%	25.9%	13.8%	85.1%
	n	92	59	33	296	131	165
	N	337	299	38	1145	951	194
Baseline lowest quartile of function (HHS)	%	25.2%	21.4%	55.3%	25.1%	24.8%	26.3%
	n	85	64	21	283	233	50
	N	337	299	38	1129	939	190
Among 1 st 25 procedures within a specific site	%	43.6%	41.8%	57.9%	20.4%	21.9%	12.9%
	n	147	125	22	234	209	25
	N	337	299	38	1148	954	194

Time to failure analysis was performed using Kaplan-Meier survival curves on the All Enrolled Cohort (N=1148). A patient remains in the survival curve until they either experience the event in question (i.e., a revision) or become “censored”. If they become lost to follow-up, or die, they are considered censored, and exit the “pool at risk” (denominator). However, they contributed information to the survival curve for as long as they were followed, even if it was less than the 2-year target. A Kaplan-Meier survival analysis was performed comparing the Cormet Hip Resurfacing System to the ceramic total hip control, for any mode of failure including femoral fracture. At 24 months the implant survival was 95.8% for Cormet vs. 99.1% for the control, Figure 1. This was statistically significant in favor of the control (p<0.01). A survival curve on the 337 subjects in the Pivotal Study unilateral cohort showed that the survival at 24 months was 95%, virtually identical to that of the All Enrolled cohort.

FIGURE 1
KAPLAN-MEIER SURVIVAL CURVE
FOR ALL ENROLLED INVESTIGATIONAL AND CONTROL DEVICES



Statistical review of the revision cohort identified the following factors as significant for revision when considering all enrolled procedures: female gender, small component size, preoperative leg length discrepancy of ≥ 1 cm, and low preoperative HHS. Twenty-one revisions occurred among the 323 procedures for female patients (6.5%) compared to 23 revisions for the 825 procedures for male patients (2.8%). Crude (single predictor variable) survival analyses accounting for unequal follow-up revealed a hazard ratio for risk of revision equal to 2.1 (95% CI 1.2 to 3.9; p=0.01) comparing females to males. There were 22 revisions for the 296 procedures (7.4%) with size 40mm or 44mm femoral components compared to 22 revisions for the 843 procedures (2.6%) for patients implanted with sizes 48mm, 52mm or 56mm [Note: implant size was unavailable for nine patients]. The hazard ratio for risk of revision was equal to 2.8 (95% CI 1.6 to 5.1; p=0.0006) comparing size 40mm or 44mm to larger sizes. When the effects of gender and size of component are simultaneously estimated in a multivariate model, component size (p=0.02) but not gender (p=0.81) retains statistical significance. Reduced baseline function was associated with increased revision risk. The hazard ratio comparing patients in the lowest quartile of HHS scores (<43) to those with higher scores was 2.0 (95% CI 1.1 to 3.6; p=0.03). Having a preoperative leg length discrepancy ≥ 1 cm was also associated with increased revision. The crude hazard ratio was 2.2 (95% CI 1.2 to 3.9; p=0.01).

Further statistical analyses revealed individual site influence and the effect of cumulative risk factors for revision. Variability across investigative sites was assessed. When all investigative sites were simultaneously assessed there was a significant site effect ($p=0.03$) that disappeared ($p=0.40$) when Site 5 (representing 15 of the 44 revisions) was removed from the analysis, indicating homogeneity of the results among the remaining sites. Statistical analyses performed with and without Site 5 provided further understanding of the risk factors for revision and the cumulative effect of those risk factors. For example, when Site 5 was removed from the analysis, the magnitude of risk for leg length discrepancy and preoperative function decreased. However, two factors, small component size and diagnosis other than osteoarthritis emerged as consistently statistically significant for both pivotal study unilateral patients and all enrolled procedures. The following table emphasizes the combined effect of these factors when analyzing revisions among patients with minimum 24+ month follow-up. Risk is smallest when neither risk factor is present, intermediate if either risk factor is present and maximum when both risk factors are present (Table 19).

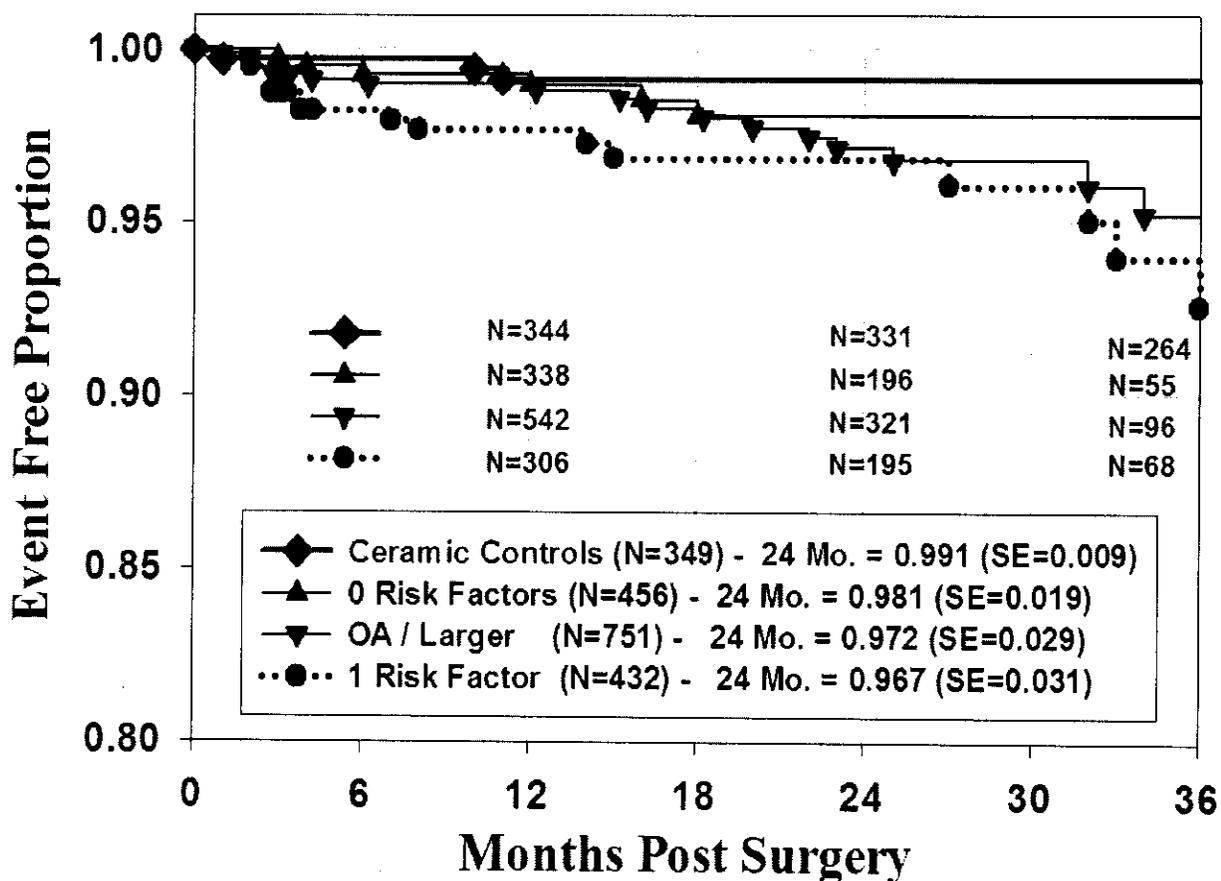
Table 19: Additive Effect of Risk Factors on Revision Rates

Diagnosis	Component Size (Correlated with Gender)	All-enrolled 24+month follow-up ¹	All enrolled minus Site 5 with 24+ month follow-up ¹	Pivotal Unilaterals follow-up to 24 months ¹	Pivotal Unilaterals minus Site 5 follow-up to 24 months ¹
OA	Larger	17/335=5.1%	8/296=2.7%	7/195=3.6%	1/169=0.6%
OA	Smaller	18/127=14.2%	12/104=11.5%	10/65=15.4%	6/55=10.9%
Non OA	Larger	5/52=9.6%	5/49=10.2%	4/32=12.5%	4/32=12.5%
Non OA	Smaller	4/18=22.2%	4/18=22.2%	3/10=30%	3/10=30%

Note: ¹ In order to provide meaningful comparisons of revision rates that accounted for varying follow-up times among subgroups, analyses were restricted to the subgroup of patients who required revision no matter when the revision occurred plus all patients who had at least 24 months of follow-up. Since this includes revisions among procedures not expected due for 24 month follow-up, revision rates in this subset are conservatively estimated.

A Kaplan-Meier survival analysis (Figure 2) was performed comparing the Corinet subjects with 0 and 1 risk factors to the ceramic total hip control. At 24 months the implant survival was 98.1% for Corinet subjects with 0 risk factors and 96.7% for those with 1 risk factor. For Corinet subjects with a diagnosis of osteoarthritis and having a larger implant size, implant survival was 97.2%.

FIGURE 2
KAPLAN-MEIER SURVIVAL CURVES
BY NUMBER OF RISK FACTORS (ALL ENROLLED)



Metal Ions

While the concerns over the local and systemic effects of metal wear products including ions exists, there is no direct evidence linking metal-on-metal arthroplasty with long-term medical problems including cancer. Increased levels of metal ions in the blood and urine of metal-on-metal total hip and resurfacing patients have been identified.^{1,2} A study performed on patients with the Cormet Hip Resurfacing System indicated that metal ion levels for cobalt and chromium initially increase following a metal-on-metal hip resurfacing but then plateau and start to decrease between one and two years post implantation. The levels remained below their peak but did not return to the preoperative levels throughout seven years of follow-up. These ion levels are similar to those reported by other authors in the metal-on-metal resurfacing systems.³ Importantly, no adverse health effects were reported as a result of increased blood metal ion levels in this study.

Effectiveness Data

The Composite Clinical Success (CCS) criteria demonstrating effectiveness includes Harris Hip Score, Radiographic Evaluation, Revisions and Adverse Events.

Harris Hip Score

Individual patient composite HHS results at Month 24 postoperatively were compared to the preoperative status.

Pivotal Study Unilateral Patients

In Tables 20 - 22 the distribution of total HHS scores collected over time is shown for the unilateral procedures in the investigational and the control group using time windows.

	Investigational Total Score					Controls Total Score					p-value ¹
	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	
Pre-Op	337	50.1	11.6	12.2	72.0	252	49.7	11.3	24.5	90.1	0.233
Week 6	329	77.4	12.4	26.4	100.0	246	79.0	11.7	40.6	100.0	0.021
Month 6	288	95.7	7.9	49.7	100.0	239	93.7	9.0	36.4	100.0	0.002
Month 12	285	96.2	7.9	41.9	100.0	246	95.0	8.0	52.3	100.0	0.002
Month 24	263	96.7	7.5	43.8	100.0	247	96.2	7.6	48.0	100.0	0.810
Month 24+	283	96.7	7.5	43.8	100.0	253	96.2	7.7	48.0	100.0	0.519
Month 36	80	96.2	7.6	66.9	100.0	187	96.0	7.7	48.6	100.0	0.619

	Investigational ROM Score					Controls ROM Score					p-value ¹
	N	Mean	SD	Min	Max	N	Mean	SD	Min	Max	
Pre-Op	337	4.37	0.57	0.83	5.00	262	4.33	0.50	2.08	5.00	0.133
Week 6	330	4.65	0.29	3.20	5.00	252	4.67	0.22	3.73	5.00	0.931
Month 6	289	4.83	0.17	4.25	5.00	243	4.86	0.16	3.40	5.00	0.242
Month 12	286	4.86	0.15	4.38	5.00	251	4.90	0.13	4.13	5.00	0.016
Month 24	263	4.86	0.17	3.85	5.00	251	4.91	0.13	3.90	5.00	0.000
Month 24+	283	4.86	0.16	3.85	5.00	254	4.91	0.13	3.90	5.00	0.000
Month 36	83	4.82	0.41	1.68	5.00	189	4.93	0.08	4.63	5.00	0.005

Notes: ¹ Wilcoxon Rank Sum Test

Table 20: Pivotal Study Unilateral Patients and Unilateral Controls: Mean Harris Hip Total and ROM Scores All Evaluated (Actual^B)

Table 21: Pivotal Study Unilateral Patients vs. Unilateral Controls: Harris Hip Pain Category All Evaluated (Actual^B)

	Preoperative		Week 6		Month 6		Month 12									
	I	C	I	C	I	C	I	C								
Hip Pain	n	%	n	%	n	%	n	%	n	%						
None	0	0.0%	0	0.0%	131	39.6%	145	55.1%	206	70.5%	166	66.4%	216	75.3%	185	71.4%
Slight	0	0.0%	2	0.8%	149	45.0%	61	23.2%	68	23.3%	53	21.2%	51	17.8%	48	18.5%
Mild	2	0.6%	7	2.6%	30	9.1%	41	15.6%	9	3.1%	24	9.6%	7	2.4%	18	6.9%
Moderate	154	45.7%	94	35.3%	18	5.4%	15	5.7%	9	3.1%	7	2.8%	10	3.5%	8	3.1%
Marked	173	51.3%	160	60.2%	3	0.9%	1	0.4%	0	0.0%	0	0.0%	3	1.0%	0	0.0%
Disabled	8	2.4%	3	1.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%

	Month 24		Month 24+		Month 36		Wilcoxon Rank Sum p-values							
	I	C	I	C	I	C	Interval	p-value						
Hip Pain	n	%	n	%	n	%	n	%						
None	212	80.6%	196	76.3%	229	80.9%	197	76.1%	68	80.0%	150	78.1%	Preoperative	0.194
Slight	39	14.8%	45	17.5%	41	14.5%	45	17.4%	12	14.1%	27	14.1%	Week 6	0.026
Mild	5	1.9%	8	3.1%	6	2.1%	9	3.5%	2	2.4%	8	4.2%	Month 6	0.174
Moderate	4	1.5%	7	2.7%	4	1.4%	7	2.7%	3	3.5%	6	3.1%	Month 12	0.290
Marked	3	1.1%	1	0.4%	3	1.1%	1	0.4%	0	0.0%	1	0.5%	Month 24	0.223
Disabled	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	Month 24+	0.162
													Month 36	0.695

Table 22: Pivotal Study Unilateral Patients and Unilateral Controls: Harris Hip Function Score Category All Evaluated (Actual^B)

	Preoperative		Week 6		Month 6		Month 12									
	I	C	I	C	I	C	I	C								
Category	n	%	n	%	n	%	n	%	n	%						
Normal (40-47)	7	2.1%	9	3.6%	58	17.7%	41	16.7%	260	91.9%	201	85.2%	263	93.3%	215	88.5%
Mild Dysfunction (40-<40)	141	41.8%	96	38.1%	88	26.8%	92	37.4%	15	5.3%	28	11.9%	14	5.0%	25	10.3%
Moderate Dysfunction (20-<30)	138	40.9%	114	45.2%	141	43.0%	97	39.4%	8	2.8%	6	2.5%	5	1.8%	3	1.2%
Severe Dysfunction (10-<20)	42	12.5%	30	11.9%	40	12.2%	16	6.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Disabled (0-<10)	9	2.7%	3	1.2%	1	0.3%	0	0.0%	0	0.0%	1	0.4%	0	0.0%	0	0.0%

	Month 24		Month 24+		Month 36		Wilcoxon Rank Sum p-values							
	I	C	I	C	I	C	Interval	p-value						
Category	n	%	n	%	n	%	n	%						
Normal (40-47)	246	93.5%	229	93.9%	264	93.3%	237	93.7%	70	88.6%	174	93.0%	Preoperative	0.981
Mild Dysfunction (40-<40)	13	4.9%	12	4.9%	14	4.9%	12	4.7%	5	6.3%	10	5.3%	Week 6	0.038
Moderate Dysfunction (20-<30)	4	1.5%	3	1.2%	5	1.8%	4	1.6%	4	5.1%	3	1.6%	Month 6	0.019
Severe Dysfunction (10-<20)	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	Month 12	0.062
Disabled (0-<10)	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	Month 24	0.879
													Month 24+	0.853
													Month 36	0.214

Pivotal Study Bilateral Group

There were no patients with a HHS < 80 in the bilateral Cormet group at Month 24 or Month 24+. Similarly, there were no bilateral procedures in the ceramic total hip control group with a HHS <80 at Month 24 or Month 24+. There was no statistical difference in HHS >80 points at Month 24 (two sided Fisher's exact test; p=0.213) or Month 24+ (two sided Fisher's exact test; p=0.130) comparing the Cormet Pivotal Study Unilateral with the Cormet Pivotal Study Bilateral groups.

There were no differences in scores at any postoperative time frame (Week 6 – Month 24+) when comparing the bilateral procedures with no more than slight hip pain to the pivotal study unilateral patient group. Both groups demonstrated no or slight pain in over 95 % of the patients at minimum Month 24.

Continued Access Group

There were two patients with HHS of <80 points at minimum Month 24 postoperative in the Continued Access group. Overall HHS results for the continued access group are included in the all enrolled group.

All Enrolled Cohort

The total HHS at Month 24 and Month 24+ were in the excellent range for both all enrolled Cormet and control groups. There was no significant difference between the groups at Month 24 in the distribution of Harris Hip Pain Score category and Harris Hip Function Score category (p=0.456 and p=0.922 respectively). In addition, there were no differences between the Cormet and control All Enrolled Procedures groups based on HHS ≥80 at the Month 24 or Month 24+ follow-up time points.

Radiographic Success

Individual patient radiographs at Months 24 and 24+ were compared to the immediate post-op radiographs (Table 23) in order to detect radiolucencies in the femoral and acetabular zones, acetabular migration, femoral subsidence and femoral tilt. There were no radiographic failures in the control group at Month 24. Table 23 summarizes the findings for the Pivotal Unilateral group at Month 24 and Month 24+.

Table 23: Radiographic Clinical Success Pivotal Study Unilateral Patients

	Month 24		Month 24+	
	N		N	
Total radiographs (Actual ^B) in Table 11 ¹	259		291	
Not available to the reviewer for evaluation ²	30		10	
Evaluable for radiographic success	229		281	
	n/N	%	n/N	%
Radiolucency Acetabular Component				
I	0 /228	0.0%	0 /279	0.0%
II	0 /228	0.0%	0 /279	0.0%
III	2 /228	0.9%	2 /279	0.7%
All ³	0 /228	0.0%	0 /279	0.0%
Radiolucency Femoral Component				
Superior	0 /229	0.0%	1 /279	0.4%
Tip	1 /229	0.4%	2 /279	0.7%
Inferior	0 /229	0.0%	1 /279	0.4%
All ³	0 /229	0.0%	1 /279	0.4%
Cup migration and tilt⁴				
Superior/Inferior migration \geq 5 mm ³	0 /228	0.0%	0 /278	0.0%
Medial/Lateral migration \geq 5 mm ³	0 /228	0.0%	0 /278	0.0%
Varus/Valgus Tilt \geq 5 degrees ³	0 /228	0.0%	0 /278	0.0%
Stem migration and tilt⁴				
Subsidence of the femoral component \geq 5 mm	7 /224	3.1%	10 /274	3.6%
Stem Tilting \geq 1 degree	172 /226	76.1%	205 /276	74.3%
Subsidence of the femoral component \geq 5 mm and Stem tilting \geq 1 degree ³	7 /226	3.1%	10 /276	3.6%
Other assessments				
Anteroversion of the head \geq 5 mm	49 /223	22.0%	55 /267	20.6%
Retroversion of the head \geq 5 mm	69 /223	30.9%	89 /267	33.3%
Hypertrophy in any zone	0 /229	0.0%	0 /279	0.0%
Resorption in any zone	0 /229	0.0%	0 /279	0.0%
Lysis in any zone	10 /229	4.4%	12 /279	4.3%
Composite radiographic failure	7 /228	3.1%	10 /279	3.6%
Notes:				
¹ Total radiographic evaluations performed for Month 24 or Month 24+ among procedures expected due. The procedures in this table were used in comparisons with control devices.				
² Not available to the independent medical reviewer for evaluation.				
³ Required for composite radiographic endpoint used in constructing the Composite Clinical Success.				
⁴ Complete component migration and tilt could not be measured for 5 cases. However, in the absence of any other indicators of failure for the component and absence of qualitative indicators of failure of the component in a serial review, these cases were not considered failure.				

Pivotal Study Bilateral Patients

A total of 55 radiographs were evaluated (58 available) for the pivotal study bilateral group at Month 24+. There were no components with a radiolucency in all zones at Month 24 or Month 24+. There was one (2.4%) cup failure based on migration and tilt criteria at Month 24 and an additional cup failure (4.1%) at Month 24+ based on these same criteria. There was one (2.3%) stem failure at Month 24 defined by both subsidence of ≥ 5 mm and tilt of ≥ 1 degree and one (3.8%) additional stem failure at Month 24+. Based on composite radiographic endpoints used in constructing the CCS, there were a total of two (4.5%) radiographic failures at Month 24 in the bilateral investigational groups and a total of three (5.7%) radiographic failures at Month 24+ in this same group.

Absence of Device Related Events

Table 24: Pivotal Study Unilateral Patients

	Investigational			Control			Exact p-value ³
	n ¹	N ²	%	n ¹	N ²	%	
Acetabular Fracture	0	337	0.0%	1	266	0.4%	0.441
Acetabular loosening	5	337	1.5%	0	266	0.0%	0.070
Avulsed lesser trochanter	1	337	0.3%	1	266	0.4%	1.000
Ceramic Insert Chip (operative)	0	337	0.0%	6	266	2.3%	0.007
Dislocation	1	337	0.3%	7	266	2.6%	0.025
Femoral Fracture (operative)	0	337	0.0%	1	266	0.4%	0.441
Femoral Fracture (post-op)	0	337	0.0%	6	266	2.3%	0.007
Femoral loosening	13	337	3.9%	0	266	0.0%	0.001
Femoral neck fx	11	337	3.3%	0	266	0.0%	0.002
Femoral subsidence	1	337	0.3%	2	266	0.8%	0.586
Trochanter (greater) fx	1	337	0.3%	0	266	0.0%	1.000
¹ Number of procedures experiencing this type of complication							
² Total population number							
³ Two-sided Fisher's Exact tests. Comparisons were not performed for femoral neck notched (operative), greater trochanter notching (operative), ceramic insert chip (operative), and femoral neck fracture since both devices were not exposed to these types of events. Also, p-values are not reported when there were no events in either group.							

Pivotal Study Bilateral Patients

Six device related events (5.7%) were reported for the Pivotal Study Bilateral Procedures in the investigational group at Month 24+ follow-up. Reasons for device related events included: acetabular loosening (one patient, 1.0%), femoral loosening (one patient, 1.0%), femoral neck fracture (two patients, 1.9%), and femoral subsidence (two patients, 1.9%).

There were no events of acetabular fractures, avulsed lesser trochanter, dislocation, intraoperative or postoperative femoral fractures or greater trochanter fracture in the bilateral investigational group.

There were six device related events (7.2%) during a comparable time frame for the Pivotal Study Bilateral Procedures in the control group. Reasons for device related events included two events of operative ceramic insert chip (2.4%), three events of dislocation (3.6%), and one event of postoperative femoral fracture (1.2%).

There were no events of acetabular fracture, acetabular loosening, avulsed lesser trochanter, operative femoral fracture, femoral loosening, femoral neck fracture, femoral subsidence, and greater trochanter fracture in the control bilateral group.

Continued Access Patients

Twenty device related events (2.9%) were reported for the Continued Access Cohort at Month 24+ follow-up. Reasons for device related events included: acetabular loosening (five procedures, 0.7%), dislocation (one procedure, 0.1%), femoral neck fracture (thirteen procedures, 1.9%), and femoral subsidence (one procedure, 0.1%).

There were no events of acetabular fracture, avulsed lesser trochanter, intraoperative femoral fracture, postoperative femoral fracture, femoral loosening or greater trochanter fracture in this cohort of procedures.

All Enrolled Patients

Fifty-nine device related events among 58 procedures were reported for the All Enrolled Cohort at Month 24+ follow-up. Reasons for device related events included: acetabular loosening (eleven procedures, 1.0%), avulsed lesser trochanter (one procedure, 0.1%), dislocation (two procedures, 0.2%), femoral loosening (14 procedures, 1.2%), femoral neck fracture (26 procedures, 2.3%), femoral subsidence (four procedures, 0.3%), and trochanter (greater) fracture (one procedure, 0.1%).

There were no events of acetabular fracture, intraoperative femoral fracture, or postoperative femoral fracture in this cohort of procedures.

Composite Clinical Success (CCS)

The criteria for CCS are as follows:

Device survival at Month 24+ as defined by a Harris Hip Score of at least 80 points at Month 24+, absence of revision of any of the components of the investigational device, absence of device related AEs, and absence of radiographic failure.

The first row of Table 25 summarizes the results of the primary non-inferiority test.

Table 25: Month 24 Composite Clinical Success (CCS)

	Investigational			Control			Non-Inferiority Test	
	N	N	Prop.	n	N	Prop.	Diff.	95% CI LB ³
Month 24+ ¹ CCS (Actual ^B)	251	292	0.860	224	256	0.875	-0.015	-0.063
Month 24+ CCS (Actual ^A) ²	246	285	0.863	223	254	0.878	-0.015	-0.062
Month 24 CCS (Actual ^B)	207	243	0.852	219	250	0.876	-0.024	-0.075
Month 24 CCS (Actual ^A)	171	202	0.847	187	209	0.895	-0.048	-0.103

Note:

1. Month 24+ outcomes are based on rollback imputations for missing Month 24 Harris Hip Scores. If the Month 24 Harris Hip Score is missing, the next available value is used (e.g., Month 36) to impute the missing value).
2. Actual^A intervals: Analyses using Actual^A intervals only include evaluations as follows: PreOp (on or before date of surgery); Immed. Interval 1-45 days; 6 Mo. Interval (6 ± 1 mo); 1 Yr Interval (12 ± 2 mo); 2 Yr Interval (24 ± 2 mo.). Actual^A Month 24+ outcomes use the rollback imputation for Harris Hip Scores and Radiographic Success. Actual^B analyses include all evaluated assessments regardless of interval boundaries.
3. Lower bounds of 1-sided 95% confidence intervals for differences between proportions with composite clinical success (Investigational minus Control). The study was designed to demonstrate clinical non-inferiority defined as a success rate no more than 0.08 smaller than control. The null hypothesis that the investigational device is inferior to the Control device is rejected if the lower bound of the confidence interval is larger than -0.08.

Among Pivotal Study Unilateral patients, 251 of 292 (proportion=0.860) patients achieved Month 24+ composite clinical success. Similarly, 224 of 256 (proportion=0.875) Unilateral Control patients achieved composite clinical success. The difference in proportions is only -0.015. The lower bound of the one-sided 95% non-inferiority confidence interval is -0.063. Since -0.063 exceeds -0.08, the null hypothesis of inferiority is rejected with $p < 0.05$ and it is concluded that the investigational device is not clinically inferior to the control device on the basis of this CCS. Additional analyses in the remaining three rows of this table provide non-inferiority results varying the follow-up restrictions. The primary analysis is the most inclusive.

Sterility

The Cormet implants are supplied sterile. The integrity of the packaging of each component should be checked carefully to ensure that product sterility has not been compromised.

- 1 These components have been sterilized by exposure to a minimum dosage and SAL of 10^{-6} .
- 2 Do NOT re-sterilize.
- 3 Inspect the packaging of ALL sterile products for flaws before opening. Assume the product is not sterile in the presence of any flaws.
- 4 Take care to prevent contamination of ANY components.
- 5 Discard ALL nonsterile or contaminated products.

Instruments used to implant the device system are supplied non-sterile and must be sterilized prior to use. After cleaning and prior to sterilization, the reusable device(s) should be double-wrapped or packaged in CSR sterilization wraps or pouches. Wrapping should be performed using the appropriate wrapping method (e.g. AAMI CSR wrapping technique).

The following sterilization method has been validated, based on AAMI/ANSI/ISO guidelines and recommendations:

- Method: Moist-Heat Sterilization
- Cycle: Pre-Vacuum (Pre-Vac)
- Temperature: 270 F (132 C)
- Exposure Time: 4 minutes
- Pressure: 2-15 PSIA
- Dry-Time: 30 minutes (minimum, in chamber)
- Cool-Time: 60 minutes (minimum, at room temperature)

After sterilizing, the reusable device(s) should be left on the sterilizer cart, untouched, for a minimum of one hour at room temperature, or until adequately cooled for safe handling.

Other sterilization methods and cycles may also be suitable. However, individuals or hospitals are advised to validate whichever method they deem appropriate at their institution. EtO sterilization and cold sterilization techniques are not recommended.

The product is not labeled “pyrogen free”.

The Cormet Hip Resurfacing System Cup components are packaged in blisters and Head components are packaged in Tyvek TM peel pouches to maintain sterility. The products have a five (5) year sterile shelf life.

Re-sterilization

Corin Group implants must not be re-sterilized and/or re-used by the customer. Any implants which, for whatever reason, are required to be re-sterilized must be returned to Corin for assessment of the feasibility for re-sterilization in accordance with the approved validated method.

The manufacturer and distributor take no responsibility for sterilization or re-sterilization of implants undertaken by the hospital.

Surgeon Education

Surgeon training will include a multi-tiered program that provides information on the importance of patient selection, identified preoperative patient risk factors, and appropriate surgical technique.

The goal of the training program is to help surgeons to develop the skills and experience with hip resurfacing using the Cormet implant system that is key to the success of this procedure as a safe and effective therapeutic solution for appropriately selected patients.

Caution: Federal Law restricts this device for sale by or on the order of a physician in the USA.

Information

For further information, please contact Corin USA Customer Service at (888) 302-6746 for calls within the continental USA and 011 44 1285 649 231 for all international calls.

Manufacturer of the Device:
Corin Group PLC
The Corin Centre
Cirencester, United Kingdom

Distributed in the US:
Stryker Orthopaedics
325 Corporate Drive
Mahwah NJ 07430

P. No lxxx Rev x Date mm yy

¹ Tipper JL, Ingham E, Jin ZM, et al. The science of metal-on-metal articulation. *Current Orthopaedics*. 2005;19: 280-287.

² MacDonald SJ, Brodner W, Jacobs JJ. A consensus paper on metal ions in metal-on-metal hip arthroplasties. *Journal of Arthroplasty*. 2004; 19:12-16.

³ MacDonald SJ. Metal-on-metal total hip arthroplasty: the concerns. *Clinical Orthopedics and Related Research*. 2004; 429: 86-93.