MicroPort Orthopedics

CERAMIC ON CERAMIC HIP SYSTEM

U.S. PRE-MARKET APPROVAL (PMA) ADDITIONAL INFORMATION

150801-0

For additional information please contact the manufacturer or local distributor.

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℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

CERAMIC ON CERAMIC HIP SYSTEM
U.S. PRE-MARKET APPROVAL (PMA) ADDITIONAL INFORMATION
(150801-0)

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GENERAL PRODUCT INFORMATION

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

- Ceramic LINEAGE®/TRANSCEND® Acetabular Liner
- SLT Ceramic Femoral Head

The Ceramic LINEAGE®/TRANSCEND® Articulation System will be implanted with the following MPO femoral stems:

- PROFEMUR® XM Cemented Stem
- PROFEMUR® LX Stem
- PROFEMUR® Renaissance Stem
- PROFEMUR® S Stem
- PROFEMUR® Tapered Stem
- PROFEMUR® Z Stem
- PROFEMUR® Plasma Z Stem
- PROFEMUR® E Stem
- PROFEMUR® Hip Stem
- PROFEMUR® R Stem
- PROFEMUR® Modular Necks
- PERFECTA® Slim Neck Plasma Coated Stem
- PERFECTA® Slim Neck IMC Stem

- PERFECTA® Slim Neck RS Stem
- PERFECTA® Slim Neck Mid-Length Stem
- PERFECTA® Plasma Coated Stem
- PERFECTA® PDA CoCr Stem
- PERFECTA® PDA Titanium Stem
- PERFECTA® PDA Calcar Stem
- PERFECTA® IMC Stem
- PERFECTA® RS Stem
- BRIDGE® Stem
- MicroPort Choice NEXUS® II Stem
- MicroPort Choice NEXUS® Nonporous Stem
- MicroPort Choice McCutchen Stem
- MicroPort Choice HA McCutchen Stem
- EXTEND® Stem **

**The EXTEND® Slim Neck stems have not been approved for use with the Ceramic LINEAGE®/TRANSCEND® Hip Articulation System.

The Ceramic LINEAGE®/TRANSCEND® Articulation System will be implanted with the following MPO acetabular shells:

- PROCOTYL™-E Shell
- LINEAGE® Spiked Shell
- LINEAGE® Multi-Hole Shell
- LINEAGE® HA Shells
- LINEAGE® Solid Shell
- LINEAGE® Quadrant Shell
- TRANSCEND® Solid Shell
- TRANSCEND® Quadrant Shell

The Ceramic LINEAGE®/TRANSCEND® Articulation System will also be implanted with commercially available MicroPort Orthopedics (MPO) apical hole plugs, and self-tapping cancellous bone screws.

Commercially Available Components

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

Ceramic LINEAGE®/TRANSCEND® Acetabular Liner

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

SLT Alumina Ceramic Femoral Head

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

***Please see additional labeling on product components.**

A. INDICATIONS

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

B. CONTRAINDICATIONS

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

C. WARNINGS

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

D. PRECAUTIONS

- Surgeons must review the training video and materials prior to implanting the Ceramic LINEAGE®/TRANSCEND® Articulation System.
- In using total joint prostheses, the surgeon should be aware of the following:

  The correct selection of the prosthesis is extremely important.

The potential for success in total joint replacement is increased by selection of the proper size, shape, and design of the prosthesis. Total joint prostheses require careful seating and adequate bone support. Smaller sized implants are intended for patients of slight weight and a low activity level. Such components could be inappropriate for other patients. Surgeons are encouraged to use their best medical judgement when choosing the proper implant size regardless of the endosteal area of the bone.

In selecting patients for total joint replacements, the following factors can be critical to the eventual success of the procedure:

1. **Patient's weight.** An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned and a small size prosthesis must be used.
2. **Patient's occupation or activity**. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
3. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
4. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be conducted prior to material selection or implantation.

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

- Consistent use of prophylactic antibiotics.
- Utilizing a laminar flow clean air system.
- Having all operating room personnel, including observers, properly attired.
- Protecting instruments from airborne contamination.
- Impermeable draping.

• Safety and Effectiveness has not been established in patients with the following conditions:
  - revision hip arthroplasty
  - inflammatory hip joint disease
  - neuropathic hip joint disease

E. ADVERSE EVENTS

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

Table 1: Reported Adverse Events

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

Other Local Complication[4]	10	1.0%	0	0%
Local - Hip	Freq.	% of Pop.	Freq.	% of Pop.
Trochanteric Bursitis	16	1.7%	1	0.5%
Trochanteric Non-union	0	0%	0	0%
Trochanteric Avulsion	4	0.4%	0	0%

Notes:

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

   Whiteside Clinical Study: Broken metal peg of acetabular cup

2. 2 were revised for this reason

3. 1 was revised for this reason.

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

Clinical Trial Information on Ceramic LINEAGE®/TRANSCEND® Articulation System

The Ceramic LINEAGE®/TRANSCEND® Articulation System is based on the Ceramic TRANSCEND® Articulation System clinical study.

Study Design

The study was a prospective, multi-center, historical control, clinical trial. The historical control group was later selected as the population from Whiteside Total Hip System clinical trial consisting of non-inflammatory degenerative joint disease cases. Study patients consisted of individuals over 21 years of age presenting for total hip arthroplasty due to osteoarthritis, congenital hip dysplasia, traumatic arthritis and avascular necrosis. A total of 329 procedures have been performed with the Ceramic TRANSCEND® device in the original pivotal clinical population (Original Clinical Population). An additional 630 devices were implanted under Continued Access. The total number (Original Clinical Population and Continued Access) meeting the inclusion/exclusion criteria as required by the protocol is 959 procedures in 848 patients. Over a two-year period, 211 hip prostheses (179 patients) with metal femoral stems and plastic cups were implanted in the Whiteside Clinical Study.

Clinical Study Patient Assessment

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

Demographics

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

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

Table 2: Patient Accounting

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

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

Table 3: Baseline and Demographics

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

Efficacy results

Table 4: Efficacy Results - HHS

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

Notes:

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

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

Any Radiographic Lucency

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

Table 5: Any Radiolucency

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

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

Implant Survivorship

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

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

Table 6: Ceramic TRANSCEND® Implant Survivorship

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

Table 7: Whiteside Clinical Study Implant Survivorship

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

Revisions and Removals

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

Patient Success Criteria

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

Table 8: Patient Success Criteria at 2 Years

Patient Success Criteria	Original Patient Population (n=329)[1]	Whiteside Clinical Study (n=211)
Absence of Revision (%)	96.7% (n=318)	98.1% (n=207)
Total HHS ≥ 70	96.8% (n=318)	95.3% (n=201)
No Complete Radiolucencies[2]	99.7% (n=328)	88.5% (n=184)

Notes:

1. The Original Patient Population sample includes procedures in the Complete Endpoint (N=309) sample plus procedures with revisions, replacements, or removals prior to Month 24 (N=9); who died prior to Month 24 (N=7); or who had only a partial Harris Hip Score assessment at Month 24 or later (N=4). This sample was constructed in order to facilitate an analysis of efficacy and safety endpoints for hips that were at-risk for a complication and that 'completed the study'. For Complete Follow-up procedures (N=329), the Month 24+

endpoint was defined as the Month 24 value and if not available, values after Month 24 were used. Original pivotal clinical population includes the first 329 procedures enrolled in the clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4)

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

Table 9: Summary of Revisions and Removals

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

Replacement of femoral head from 32mm to 28mm	50/M	Osteoarthritis	1 day	Liner/head size mismatch noted on postoperative film
Replacement of (uncemented) femoral stem to cemented stem	56/M	Osteoarthritis	657 days	Pain and progressive subsidence due to undersized (uncemented) femoral stem
Replacement of femoral stem and head	56/F	Osteoarthritis	786 days	Femoral component loosening

F. HANDLING AND STERILIZATION

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

This product is for single use only. Prosthesis should never be reused. While it may appear undamaged, microscopic imperfections may exist which would reduce the service life of the prosthesis. Prosthesis should never be resterilized or reused after contact with body tissues or fluids, but rather should be discarded.

Warning: Do not resterilize ceramic acetabular liner.

Warning: Do not resterilize ceramic femoral heads.

Warning: Do not resterilize protheses with HA coated surfaces.

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

If sterilization of the metal acetabular shell is required, proceed accordingly.

The following sterilization recommendation has been developed using specific equipment for a SAL of 10^{-6} and may vary depending on processing conditions, wrapping materials, or equipment. The cycle and conditions must be demonstrated to produce sterility in your environment.

1. Disassemble components prior to sterilization.
2. Wrap the component in non-woven medical grade wrapping material or place in a sealed sterilization pouch. If using a 270°F (132°C) pulsing vacuum cycle, the component may also be placed on a standard mesh sterilization tray.
3. Autoclave according to the following parameters:

Method	Cycle	Temperature	Exposure
Steam	Gravity	250°F (121°C)	30 minutes
Steam	Pulsing Vacuum	270°F (132°C)	5 minutes

After sterilization, remove the component from its packaging or the sterilization tray 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.

G. CONFORMANCE TO STANDARDS

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

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

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

ISO 10993-7: 1995, Biological Evaluation of Medical Devices-

Part 7: Ethylene oxide sterilization residuals

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

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

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

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