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INSTRUCTIONS FOR USE / WARNINGS AND PRECAUTIONS
Stelkast Surpass™ Acetabular System

DEVICE DESCRIPTION

The Stelkast Surpass™ Acetabular System is a total hip replacement system that consists of the following components:

- The Stelkast Surpass™ Ceramic Femoral Head, available in 28 mm and 32 mm diameters, and three neck lengths (short / -3.5mm, medium / 0mm, and long / +3.5mm). The heads are manufactured from high purity, dense aluminum oxide (alumina - Al_2O_3) ceramic (ASTM F603).

- The Stelkast Surpass™ Ceramic Acetabular Liner, available in corresponding sizes. The liner used with the 28 mm head is referred to as the 28-46 liner and is designed to fit shells of 46, 48, and 50 mm outer diameter only. Two liners are available for use with a 32 mm head, one (the 32-52 liner) is designed to fit shells of 52, 54, and 56 mm outer diameter, and the other (32-58 liner) is designed to fit shells of 58, 60, 62, 64, 66, 68, 70, and 72 mm outer diameter. The liners are also made from alumina ceramic.

- The Stelkast Surpass™ Acetabular Shell, available in 14 sizes, ranging from 46 mm to 72 mm in 2 mm increments. The shell is hemispherical and manufactured from titanium alloy, Ti-6Al-4V ELI (ASTM F136). The outer surface of the shell is coated with a porous plasma-sprayed commercially pure titanium powder (ASTM F1580). The 46 mm shell includes 2 holes for additional screw fixation, whereas all other shells include a cluster of 3 screw holes. The shell utilizes a taper lock to achieve fixation with the mating ceramic liner. The shell is intended for cementless use.

The Stelkast Surpass™ Acetabular System is implanted with self-tapping cancellous bone screws. The Stelkast 6.5 mm acetabular screws vary in length from 15 mm to 60 mm. The screws are manufactured from titanium alloy, Ti-6Al-4V (ASTM F1472). These screws have been modified from previous Stelkast designs by reducing the head profile to prevent impingement with the ceramic liners.

The Stelkast Surpass™ Acetabular System is implanted with the Protract, ProClass, or Provident femoral hip stems from Stelkast. The Provident and Protract stems are made from titanium alloy, Ti-6Al-4V ELI alloy (ASTM F136), while the ProClass stems are made from Ti-6Al-7Nb alloy (ASTM F1295). The Protract and Provident stems have a proximal porous plasma sprayed titanium coating. The Protract stem is also available in a porous plasma spray with hydroxyapatite (HA) coating. All three stems have a 12/14 neck taper to mate with the corresponding Surpass™ Ceramic Femoral Heads and are intended for cementless press-fit fixation.

INDICATIONS FOR USE

The Stelkast Surpass Acetabular System is indicated for cementless use in primary total hip arthroplasty in skeletally mature individuals with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and traumatic arthritis.

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CONTRAINDICATIONS

The Stelkast Surpass Acetabular System is contraindicated in patients with:

- overt or latent infection in or around the hip joint,
- insufficient bone stock to allow appropriate insertion and fixation of the prosthesis,
- insufficient soft tissue integrity to provide adequate stability,
- muscle laxity or inadequate soft tissue for proper function and healing,
- neuromuscular disorders that do not allow control of the affected joint,
- skeletally immature patients.

WARNINGS

- Do not allow damage to the polished bearing surfaces because this may accelerate wear of the components. Any alteration or damage to a component may reduce fatigue strength and could result in failure under load. Any prostheses so damaged must not be used.
- Avoid excessive use of force when seating the ceramic head on the trunnion, as this could result in fracture of the ceramic head.
- Seat the acetabular shell at a 45° inclination with 20° anteversion for proper positioning to decrease the possibility of dislocation. Care should be taken to avoid femoral neck-acetabular impingement in all potential positions. The acetabular component should be repositioned as necessary to relieve impingement. Improper position of the components could result in dislocation or fracture of the components.
- Only Stelkast acetabular screws should be used with Stelkast Surpass Acetabular Shells. To ensure proper ceramic liner seating in the shell, all screw heads must be seated below the inner surface of the shell.
- Always ensure proper alignment and seating of the Stelkast Surpass Acetabular Liner before impacting to prevent chipping or damage. Full and unobstructed seating is crucial to implant fit and longevity.
- Do not disassemble and reassemble the ceramic liner to the acetabular shell as the taper joint may become deformed during this process. Damage to the shell taper may affect the locking mechanism between the liner and shell and increase the risk of ceramic liner fracture.
- Do not scratch or dent the rim or internal taper of the acetabular shells. If the rim or taper joint is damaged during implantation, the acetabular shell should be replaced, as the deformation of the shell taper may affect the locking mechanism between the liner and shell and increase the risk of ceramic liner fracture.
- If the ceramic liner is chipped, scratched, or otherwise damaged during the implant procedure remove **both** the liner **and** shell and do not reuse. The liner should be removed because the damage can lead to stress risers within the material which can increase the risk of ceramic liner fracture. The acetabular shell should be removed because its metal taper should not be reassembled with a new ceramic liner once it has been deformed by assembly/disassembly with the original ceramic liner. A deformed metal taper could significantly affect the locking mechanism between the new liner and shell and increase the risk of ceramic liner fracture.
- To prevent a mismatch of the tapers, do not use other manufacturers' components with any of the Stelkast Surpass Acetabular System components. **Use only compatible Stelkast components with the Stelkast Surpass Acetabular System** (see product literature for list of appropriate components).
- Do not implant in obese patients because loading on the ceramic components may lead to fracture or loss of fixation.
- Implants are for single use only. Do not reuse an implant.
- Do not re-sterilize components. Return all packages with flaws to the manufacturer.

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PRECAUTIONS

- Familiarity with and attention to appropriate surgical technique for hip joint arthroplasty and the Stelkast Surpass Acetabular System is essential for success of the procedure.
- Only surgeons who have reviewed the literature regarding hip surgery and have had training in the technique should utilize the device. Patient selection is based on age, bone stock and size. The surgeon or designee should instruct patients in the limitations of the prosthesis, and these patients should be taught to govern their activities accordingly. Patient lifestyles must be evaluated by the physician, and patient properly advised of any required modifications.
- Clean surgical debris from the interior of the shell prior to seating the liner into the shell to prevent accelerated bearing wear. Accelerated bearing wear may lead to early failure of the device.
- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.
- Clean and dry surfaces that 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 Stelkast Surpass Acetabular Liner because this may accelerate bearing wear and lead to early failure of the device.
- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall with screws that are too long can result in internal bleeding and possible damage to vital organs.
- Avoid detachment of titanium or hydroxyapatite coatings, which could lead to increased debris particles.
- Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular liner.
- Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- In order to prevent sepsis, the physician is advised to follow the following recommendations:
  - Consistently use prophylactic antibiotics.
  - Utilize a laminar flow clean air system.
  - Have all operating room personnel, including observers, properly attired.
  - Protect instruments from airborne contamination.
  - Use impermeable draping.
- Safety and Effectiveness have not been investigated in patients with the following conditions:
  - revision hip arthroplasty
  - inflammatory hip joint disease
  - neuropathic hip joint disease

POTENTIAL ADVERSE EFFECTS ASSOCIATED WITH TOTAL HIP ARTHROPLASTY

As with all hip joint implant systems, potential adverse effects include infection, loosening of the components, breakage, bending or disassembly of the components, or change in position of the components. There have been reports of sensitivity reactions to the metal implant components. Other potential adverse effects of hip implant joint surgery include histological reactions involving macrophages and fibroblasts, detachment of the porous coatings which can lead to increased debris particles, hematoma, neurovascular damage, lengthening or shortening of the limb, traumatic arthrosis of the hip from intraoperative positioning of the limb, delayed wound healing, inadequate range of motion due to improper selection or positioning of components by femoral impingement and/or periarticular calcification, dislocation, thromboembolic disease, acetabular pain, component failure, wear debris, periprosthetic bony fracture, and other less common adverse effects. On rare occasions, amputations and deaths have been reported.

POTENTIAL ADVERSE EFFECTS ASSOCIATED WITH THE SURPASS ACETABULAR SYSTEM

In addition to the adverse effects identified above, additional adverse effects may be associated with the Stelkast Surpass Acetabular System. The Stelkast Surpass Acetabular System utilizes alumina

ceramic for both bearing surfaces (femoral and acetabular). Potential adverse effects that have been reported with the use of ceramic-on-ceramic bearing surfaces include wear, fracture, cracking, or chipping of the ceramic components. While rare, higher rates of wear may be initiated by particles of cement, metal, or other debris that can cause abrasion of the articulating surfaces. Fracture, cracking, or chipping of the ceramic components can also occur as a result of improper alignment, trauma, strenuous activity, or impingement. See Table 3 for a detailed listing of all adverse events reported in the clinical study of another hip system (FDA Premarket Approval Application (PMA) P010001) that utilizes the same ceramic bearings as the Stelkast Surpass Acetabular System.

CLINICAL TRIAL INFORMATION ON STELKAST SURPASS ACETABULAR SYSTEM

The ceramic components of the Stelkast Surpass Acetabular System are identical to those in the Ceramic TRANSCEND Articulation System. The clinical data on the TRANSCEND System (reported in FDA Premarket Approval Application P010001) are relevant to the Stelkast System because the two systems have identical articulating surfaces and yielded similar results in bench top testing.

Clinical Study Design

The study was a prospective, multi-center, historical control, clinical trial. The historical control group was later selected as the population from the 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 P010001 Clinical Trial 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 was 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 six, twelve, 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 twelve 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 were 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 1 and 2. Note that there were seven deaths, none of which were related to the study or to the device.

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Table 1. 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=2%33)
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 2. 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, degrees (range 0-5)	3.8 (range -3.1-4.88)	4.1 (range not available)

Safety Results

The adverse events related to total hip replacement surgery reported in the P010001 clinical study of 959 procedures are listed in Table 3.

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Table 3. Reported Adverse Events

Event	P010001 Clinical Study (n=959)		Whiteside Clinical Study (Control) (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.**
Revisions/Removals[1]	11	1.1%	8	3.8%
Breakage/Fracture of Component[2]	5	0.5%	2	0.9%
Dislocation (single) of Component[3]	8	0.8%	3	1.4%
Dislocation (recurrent) of Component[4]	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[5]	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] See details in the following Table 4 for n=959.
[2] Clinical Study: Chipping of ceramic acetabular liner during placement requiring intraoperative revision. Whiteside Clinical Study: Broken metal peg of acetabular cup.
[3] 2 were revised for this reason.
[4] 1 was revised for this reason.
[5] 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.

Revisions and Removals

Eleven devices out of the 959 procedures in the trial have been revised or removed. Table 4 summarizes the clinical information pertaining to these cases.

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Table 4. 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

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Efficacy Results
Table 5, below, shows the mean and range of Harris Hip Scores for each study cohort preoperatively and at two years postoperatively.

Table 5. 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 whether they involved the entire Gruen zone (seven AP femoral zones, seven lateral femoral zones, three AP acetabular zones, and three lateral acetabular zones). Table 6 summarizes these results.

Table 6. 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 P010001 Clinical Trial. Kaplan-Meier cumulative survivorship is shown in Tables 7 and 8 for the P010001 Clinical Trial and the Whiteside hip over time.

The cumulative Kaplan-Meier survivorship values for the femoral or acetabular component are shown in Tables 7 and 8 based on the longest duration of follow-up available in each study cohort.

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Table 7. P01001 Clinical Trial 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 8. 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

Patient Success Criteria

Table 9 describes the proportion of patients meeting individual clinical success criteria at two years postoperatively.

Table 9. Patient Success Criteria at Two 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.

STERILITY AND HANDLING

Each component of the Stelkast Surpass Acetabular System is supplied sterile in double sealed containers maintaining double sterile barriers. If the seals or containers are breached, then the component should not be used. The components are not represented to be "pyrogen-free."

Metal and ceramic parts are supplied exposed to a minimum of 25 kGy (2.5 Mrad) of gamma irradiation and must be kept unopened in the double protective packaging until implantation. The sterile container is to be checked for possible damage. Do not use any component if the packages have been breached.

Resterilization by any method is ruled out.

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Care should be utilized in the handling of the components to minimize contamination of the component surfaces. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials.

UTILIZATION AND IMPLANTATION

Selection of the Stelkast Surpass Acetabular System depends on the judgment of the surgeon with regard to the relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prostheses by (1) appropriate reading of the literature, and (2) training in the operative skills and techniques required for hip joint arthroplasty surgery. Please see the Surpass Acetabular System surgical technique manual for device-specific instructions regarding the proper implantation and removal techniques for these components.

MATERIALS USED

The materials used are listed on the respective product labels.

PATIENT COUNSELING INFORMATION

Complications and/or failures of total hip prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear, and/or fracture of the hip implant. The prospective implant patient must be counseled about the capabilities and limitations of the implant and the impact it will have on their lifestyle. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities and about the possibility that the implant or its components may wear out, fail, or need to be replaced. It must be emphasized that these implants are manufactured from metal and ceramic materials and that any joint replacement, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. The implant may not, and is not guaranteed to, last the rest of the patient's life, or any specified length of time. Because prosthetic joints are not as strong, reliable, or durable as a natural, healthy joint, all prosthetic hips may need to be replaced at some future point.

INFORMATION

For any further information, please contact the supplier. Please be sure to refer to the Catalog Number designated with REF.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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Draft Patient Labeling
Stelkast Surpass Acetabular System

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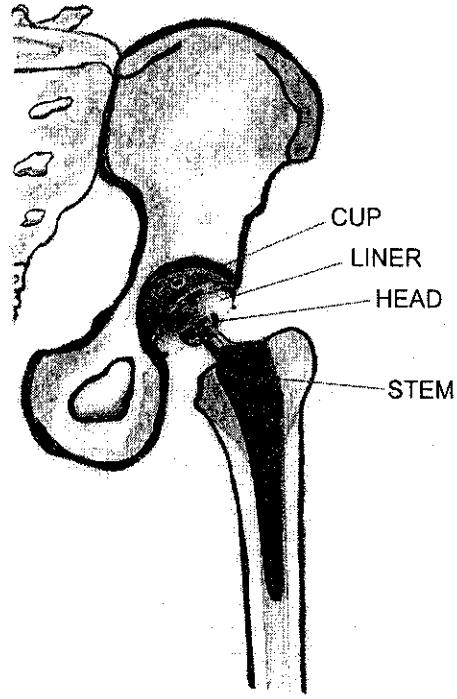
What is the device?

The hip system is the Stelkast Surpass™ Acetabular System and is composed of the following parts: the Surpass ceramic liner and ceramic femoral head, titanium acetabular shell, and a compatible Stelkast metal hip stem. Your hip replacement with ceramic parts includes the ceramic socket (liner) which fits into the titanium shell (cup), and a ceramic ball (head) that fits on the top end of the metal stem. The ceramic head slides around within the ceramic liner, which allows this artificial hip replacement system to move.



(Note: In final version of labeling, a ceramic/ceramic illustration will be used)

What is the purpose of the device?

The Stelkast Surpass Acetabular System is indicated for cementless use in total hip joint replacement for reduction or relief of pain and/or improved hip function in skeletally mature individuals with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and traumatic arthritis. These diagnoses are defined below:

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

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

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

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

What happens during the implant procedure?

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

When should the device not be used (Contraindications)?

Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit. Absolute contraindications include:

- obvious infection;
- distant centers of infections (which may be spread through the blood stream or circulation to the implant site);
- rapid disease progression as obvious by joint destruction or bone absorption (loss of bone) seen on x-ray photographs;
- patients whose bones have not stopped growing;
- cases where muscles may be too weak to work satisfactorily (e.g., prior paralysis [loss of function] and fusion [joining together]), poor bone stock (weak bones), poor skin coverage around hip joint causing the procedure to be unadvised;
- inflammatory degenerative joint disease (like rheumatoid arthritis);

- joints with nerve disorders;
- patients who are obese;
- nerve or muscle disease that may negatively have an effect on gait (walking) or weight bearing.

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

What are the risks and benefits?

While there can be no guarantee of success, benefits can include the potential relief of pain and return of normal use of the hip. There is also the possibility for this ceramic bearing replacement to outlast the standard replacements currently being used.

The risks and complications associated with this hip replacement are expected to be similar to those of other hip replacements. Each of these reactions/complications can arise during and after surgery and may require medical intervention (such as surgery) and/or implant removal. The risks and complications include:

- Advancing bone breakdown and loss may occur around the hip implant parts due to foreign body reaction to particles.
  - Particles of hip implant materials, cement, and bone are generated by contact between hip implant parts and contact between hip implant parts and bone.
  - Particles may be caused by bonding (attachment), scraping, and/or breakage.
  - Particles in between the hip implant parts or between the hip implant parts and bone may cause more particles of implant materials or bone to be formed at an increasing rate.
  - Particles may migrate to other parts of the body.
  - Osteolysis (dissolving of bone) can lead to future problems such as removing or replacing the hip implant parts.
- Wear of the alumina ceramic joint surfaces of hip parts has been reported following total hip replacement. Higher rates of wear may be caused by particles of cement, metal, or other debris, which can cause scraping of the joint surfaces. Higher rates of wear may shorten the useful life of the hip, and lead to early revision surgery to replace the worn out hip parts.
- Although rare, metal allergy reactions in patients following hip surgery have been reported. The presence of any implant material can be seen as foreign and the body tissue may react against it.
- Nerve damage, without clinical signs or symptoms, has been reported, and may occur as the result of having hip surgery.
- Dislocation and subluxation (partial dislocation) of hip parts can result from improper positioning of the components. Muscle and rubbery tissue laxity (slackness) can also contribute to these conditions.
- Hip parts can loosen or migrate (move) due to trauma or improper attachment.
- Infection can lead to failure of the hip joint.
- While rare, fatigue fracture (breakage) of the hip parts can occur as a result of trauma, strenuous activity, improper position, or time implanted in the body (service life).

What might increase the risk of failure?

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

What are the complications that may occur during surgery or shortly after?

- pain;
- femoral or acetabular perforation (hole in hip parts), or broken bones;
- broken bone while seating the device;
- damage to blood vessels;
- temporary or permanent nerve damage resulting in pain or numbness of the affected limb; and
- undesirable shortening or lengthening of the limb caused by improper selection of the implant size;
- traumatic arthrosis (disease of the joint) of the hip from intraoperative positioning of the extremity;
- 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; and
- infection.

What kind of problems could happen later on?

- pain;
- trochanteric avulsion (where a small piece of the thigh bone is pulled away) as a result of excess muscular tension, early weight bearing, or accidental weakening during surgery;
- trochanteric non-union (broken bone that does 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 enough muscle;
- broken bone by trauma or excessive loading (weight or force), particularly in the presence of poor bone stock;
- periarticular calcification (calcium deposits around a joint) or ossification (bone

formation) with or without obstacles to joint mobility (able to move); and
- inadequate range of motion due to improper selection or positioning of hip parts, by femoral impingement (parts striking each other), and periarticular calcification (calcium deposits around a joint).

What role does the patient have?

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

When should the patient contact the doctor?

You should contact your doctor immediately if you experience any of the following symptoms:
- Redness, swelling, or drainage from around your incision,
- An unexplained fever (temperature over 100 degrees Fahrenheit or 38 degrees Centigrade) or chills that last more than a day,
- Severe hip pain that is not relieved by your pain medicine,
- Any unusual shortening or rotation (turning) of your leg, or
- Any sudden swelling in your thigh or calf.

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

What Alternatives does the patient have?

Depending on individual circumstances, alternative procedures may include the use of other commercially available total hip replacement parts already approved or cleared by FDA; non-surgical treatment such as reduced activity and/or pain medication; or other surgical treatments that do not involve the use of an implant.

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