

ProForm™/Provident™ Acetabular Cups

Surgical Protocol and Product Specifications



ProForm™/Provident™ Acetabular Cups

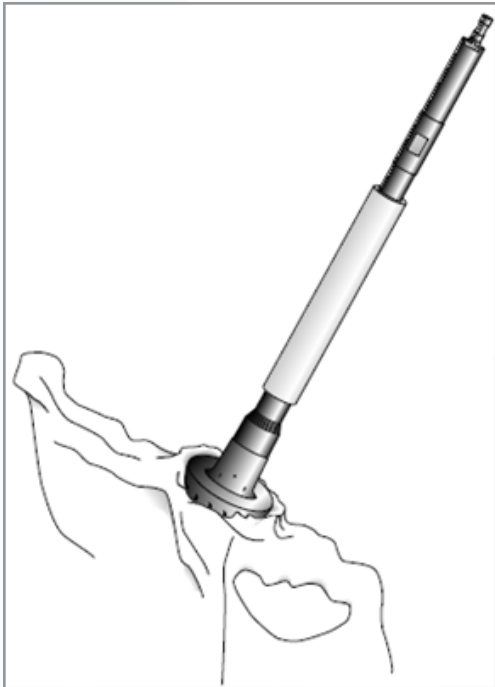


Figure 1
Preparation of Acetabulum with Reamers

Introduction

StelKast offers a variety of acetabular options to meet the needs of today's orthopedic surgeons. The modular acetabular system consists of a Titanium shell and a polyethylene liner. The outside of the shell is hemispherical with a rim flare at the circumference and is textured with either porous beads or plasma spray. No hole, cluster hole or multiple hole configurations are available. Each shell includes a permanently assembled retaining ring to firmly hold the polyethylene liner, while allowing for easy removal of the liner if required.

Acetabular Preparation

Once the acetabular labrum and redundant capsule are removed, the floor of the cotyloid fossa is identified. Commonly this is crowded with osteophytes which are removed with a large curette. This portion of the nonarticular floor of the acetabulum clearly delineates the extent of the medial wall inferiorly. Reaming confluent with this level will medialize the component without perforation of the medial wall. Reaming is begun approximately 6-8 mm less than the templated size. The initial reaming is done and the reamer orbited to remove the cartilaginous debris. Sequential reaming is done in 1-2 mm increments with attention to the thickness of the acetabular walls (**Figure 1**). When thinning is present, the reamer should be pulled toward the opposite wall to avoid the generation of a rim defect. In addition with increasing reamer diameter the position of the reamer should mimic the final position of the acetabular component. The finished acetabulum should have the

cotyloid fossa removed and the acetabular rim snug against the finishing reamer. The tightness of the fit can be trialed with the acetabular trials. The trial equal in diameter to the last acetabular reamer should be used. This will provide line to line fit with the trial shell. An implant equal to the reamer size will provide a line to line fit in the hemisphere region and a 1.25 mm total interference rim fit. It is recommended that the spherical difference between the reamer and shell not exceed 1 mm due to the flared rim of the acetabular shell.

Acetabular Component Insertion

Insertion of the Acetabular Shell

The acetabular components can be used with or without screws. This can be accomplished by selecting a shell size equal to the reamer diameter or by using a shell that is 1 mm larger than the reamer diameter for a tighter fit. Note that shell sizes are available in even numbers with 2 mm increments.

Once the appropriate size acetabular shell is selected and opened on the sterile field, it can be placed on a table with the inner surface of the shell face up. The alignment arrow on the shaft of the inserter is to be aligned with the retaining ring window in the rim of the cup. Place the expanding end of the inserter into the circumferential groove located on the inner surface of the shell. A quarter turn of the knob located in the middle of the inserter will lock the shell in place (Figure 2).



Figure 2
Attachment of Acetabular Inserter to Shell

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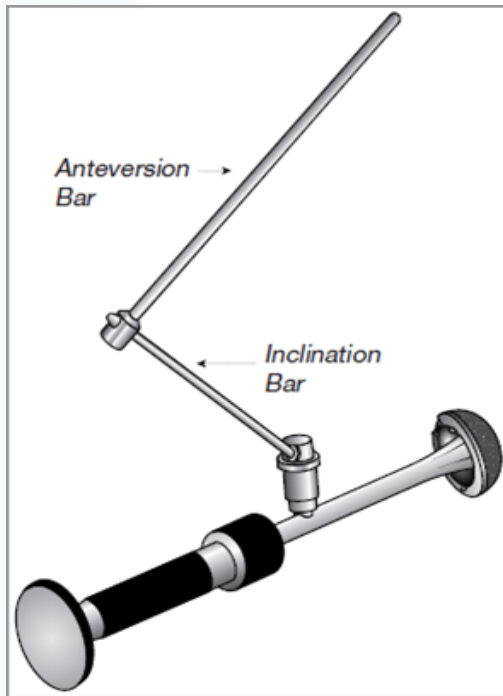


Figure 3 Acetabular Shell Insertion with Orientation Guides

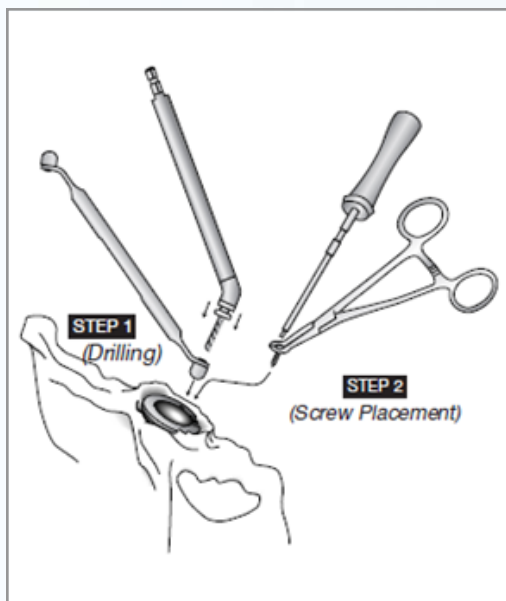


Figure 4
Preparation for and Insertion of Screws

The shell inserter is then positioned in the acetabulum to ensure anatomical placement of the shell. As a reference, the orientation guides on the shell inserter indicate 45 degrees of abduction (inclination bar) and 20 degrees anteversion (anteversion bar) (Figure 3). The shaft of the inserter should point to the posterior-superior iliac spine. Light blows are used to engage the acetabular rim while frequent checks are made on the position of the component.

The acetabular shell can be disengaged from the inserter-extractor at any time and readily reattached as needed. When the rim is engaged and the desired position is achieved, the shell is seated with firm impacts.

Screw Fixation

The acetabular components have either cluster or multiple hole options. When a snug fit cannot be obtained on trial or acetabular defects will not allow a rim fit, an acetabular component with screws should be used. Screws are available in 5 mm increments from 15 mm to 40 mm and in 10 mm increments from 40 mm to 60 mm.

Once the cup is seated in the acetabulum, the drill guide can be placed into the screw hole on the inside of the acetabular shell. A suitable drill bit can then be carefully inserted into the drill guide to prepare the bone for the screw (Figure 4, Step 1).

After drilling, the depth gauge can be inserted into the screw hole to determine the appropriate length screw. Once the screw is selected, it can be grasped with the screw holding forceps and inserted into the acetabular shell (Figure 4, Step 2). The selected screwdriver shaft and ratchet handle can be assembled and used to drive the screw into the bone. Ensure that the screw head is below the inner surface of the shell.

Note: If using a flexible drill, the screw holding forceps can be used to apply a downward force on the drill. The flexible drills should not be operated in reverse.



Figure 5
Insertion of Acetabular Liner or Trial

Insertion of the Polyethylene Liner

A hooded or non-hooded trial liner can be trialed for position and stability. The appropriate acetabular liner is then dialed into position. The liner is secured when it is pushed into the shell and locked by the retaining ring. The force necessary to seat it can be applied using digital pressure only (Figure 5). If any seating resistance is encountered, the liner is withdrawn and the shell examined for debris or soft tissue impingement.

Extraction of the Polyethylene Liner

Occasionally at the time of final trial reduction it may be desirable to rotate the liner due to malpositioning. The polyethylene liner may be withdrawn from the shell using the liner retaining ring forceps to expand the retaining ring (Figure 6). This extraction should not harm either the liner or the shell. The liner is then withdrawn, repositioned and resealed.




Figure 6
Removal of Polyethylene Liner if Required

GENERAL PRODUCT INFORMATION

Through the advancement of partial and total hip joint replacement, the surgeon has been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal, ceramic, and plastic materials and that any joint replacement, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system will not be as strong, reliable, or durable as a natural human joint.

INDICATIONS FOR USE


Stelkast Company hip implant components are indicated  for single use only in skeletally mature individuals undergoing reconstruction of severely disabled and/or very painful joints. If cemented fixation is required for the component being used, then the respective component label will include the statement; "This device is intended for cemented use only." Stelkast Hip System components are indicated for either cemented or cementless use for reconstruction of the articulating surface of the femoral and/or acetabular portions of the hip that are severely disabled and/or very painful resulting from non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, traumatic arthritis, correction of functional deformity, treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement unmanageable using other techniques. The components can be used for primary hip implant or for hip revision of a failed total hip arthroplasty.

CONTRAINDICATIONS

Stelkast Company hip implant components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, patients without sufficient soft tissue integrity to provide adequate stability, muscle laxity or inadequate soft tissue for proper function and healing, any pathological conditions that would interfere with the performance of the system and in patients with either mental or neuromuscular disorders that do not allow control of the affected joint, and in patients whose weight, age or activity level might cause extreme loads and early failure of the system. The Biolox Delta and Zirconia ceramic heads are contraindicated for use with any other than an UHMWPE cup or metal backed UHMWPE cup

WARNINGS AND PRECAUTIONS

Familiarity with and attention to appropriate surgical technique for hip joint arthroplasty and the Stelkast implant system is essential for success of the procedure. Improper position of the components could result in dislocation. 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 his 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.

 Hip implant components must not be reused. The surgeon must not allow damage to 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. In the case of hip cup revisions in which the hip stem is not revised, ceramic femoral heads could break because of trunnion damage or mismatch. Care must be taken when ceramic heads are implanted to avoid overuse of force during seating the head on the trunnion. The stem trunnion and head bore should be dry and free of contamination prior to assembly of a ceramic head to the trunnion.

Components of Stelkast Company hip implants should not be used with those of another manufacturer since articular and dimensional compatibility cannot be assured, including possible femoral head taper mismatch. **Only Stelkast femoral heads should be used with Stelkast hip stems.**

Hip implant components have not been evaluated for safety and compatibility in the MR environment. Hip implant components have not been tested for heating or migration in the MR environment.


ADVERSE EVENTS

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 implant components. Other potential adverse effects of hip implant joint surgery include neurovascular damage, dislocation, thromboembolic disease, acetabular pain, component failure and wear debris and other less common adverse effects. On rare occasions, amputations have been necessary.

STERILITY AND HANDLING

Each Stelkast Company hip implant component 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 as well as polyethylene (UHMWPE) parts and/or components containing polyethylene or polymethylmethacrylate (PMMA) are supplied exposed to a minimum of 2.5 Mrad of gamma irradiation or Ethylene Oxide sterilization and must be kept unopened in the double protective packaging until implantation. The sterilization method used is listed on the respective component label. 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.

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. In using cement for fixation, the surgeon should use care to ensure complete cement support on all parts of the prosthesis embedded in bone cement.

UTILIZATION AND IMPLANTATION

Selection of Stelkast Company hip implant components 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.

MATERIALS USED

The materials used are listed on the respective product label.

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.

ProForm™/Provident™ Acetabular Cups

Product Specifications

Acetabular Shell / Liner

- Titanium Shell with textured finishes
 - Titanium plasma spray
 - Titanium porous bead
- Locking ring to secure liner
- Congruent high luster finish ID
- Snap-in Polyethylene liner
- Clustered, multiple and no-hole designs
- Moderately Cross-linked ProAr™ Polyethylene
- Highly Cross-linked EXP™ Polyethylene
- Non-hooded and 10° Hooded Options



Shells

ProForm™ Porous Beaded			Provident™ Plasma Sprayed
No Hole SC1408-100	Cluster SC1408-200	Multi-Hole SC1408-300	Cluster SC1217
46	46	60	46
48	48	62	48
50	50	64	50
52	52	66	52
54	54	68	54
56	56	70	56
58	58	72	58
60	60	74	60
62	62	76	62
	64		64
	66		66
	68		68
Indicates Special Order Components			70
			72

Screws

6.5mm SC1156* / SC2677
15
20
25
30
35
40
50
60



Indicates
Special
Order
Components

* SC1156 Screws are not for use with Surpass™ Acetabular System.

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Product Specifications (continued)

Liners



ProAr™				Exp™ XLPE					
Non-Hooded		Hooded		Non-Hooded			Hooded		
28mm SC2542	32mm SC2397	28mm SC2543	32mm SC2398	28mm SC3342	32mm SC3344	36mm SC3260	28mm SC3343	32mm SC3345	36mm SC3349
4648		4648		4648			4648		
5052	5052	5052	5052	5052	5052		5052	5052	
5456	5456	5456	5456		5456	5456		5456	5456
5860	5860	5860	5860		5860	5860		5860	5860
6264	6264	6264	6264		6264	6264		6264	6264
6668	6668	6668	6668		6668	6668		6668	6668
7076	7076	7076	7076			7076			7076

Indicates Special Order Components

Femoral Heads



CoCr			BIOLOX® delta Ceramic		
28mm SC1151/ SC1152	32mm SC2271/ SC2272	36mm SC3261/ SC3346	28mm SC3347	32mm SC3348	36mm SC3295
-5					
-3.5	-3.5	-3.5	-3.5	-3.5	-3.5
+0	+0	+0	+0	+0	+0
+3.5	+3.5	+3.5	+3.5	+3.5	+3.5
+7	+7	+7		+7	+7
+10.5	+10.5	+10.5			
+12					

* BIOLOX® delta Ceramic Heads are not for use with Surpass™ Acetabular System.



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