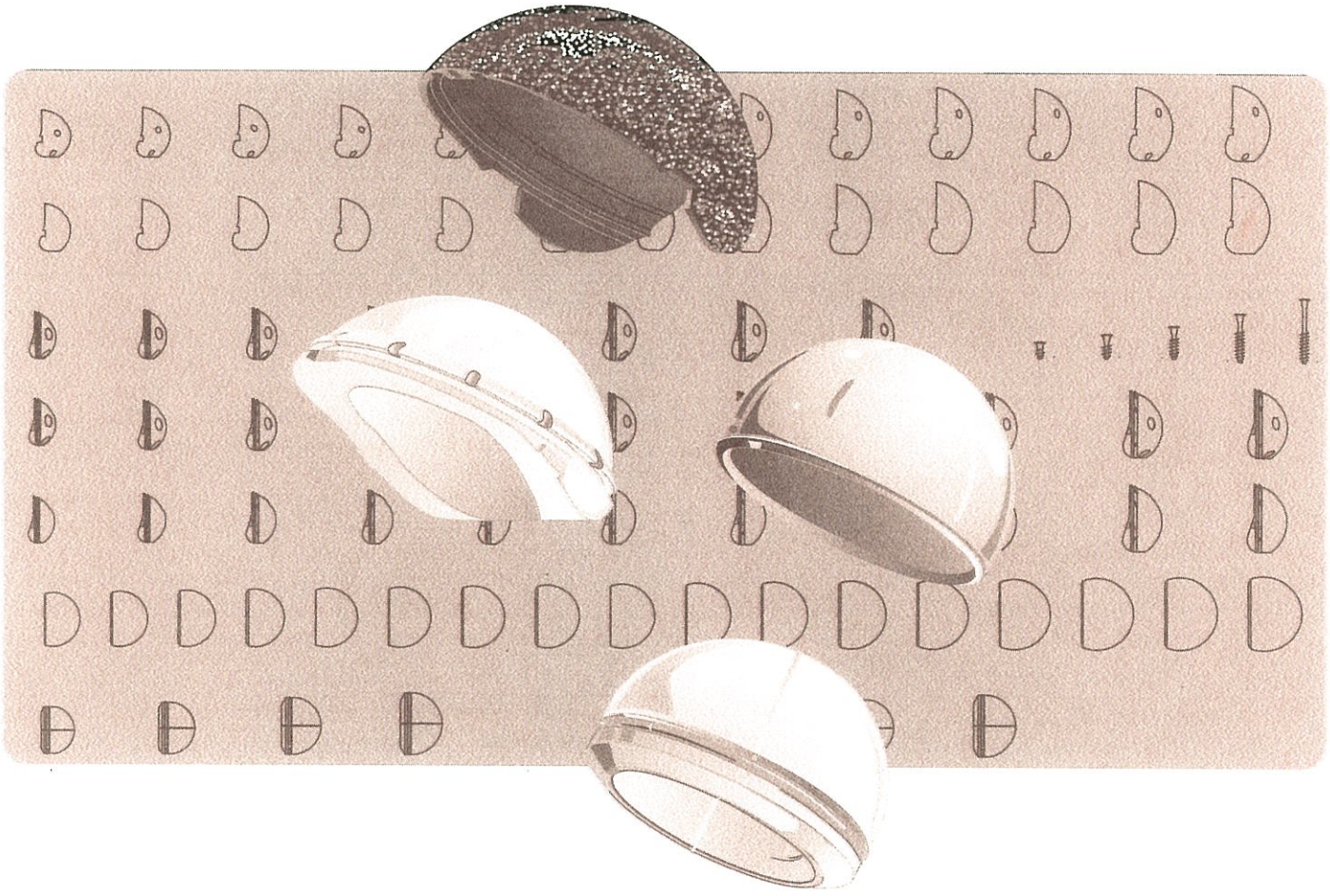
Tripolar Total Hip Replacement

Stability Range of Motion Resistance to Wear



Surgical Concepts

Introduction

Tripolar Total Hip Arthroplasty is done by matching a polyethylene hip resurfacing socket with a bipolar femur. This was first found useful when treating a femoral neck fracture or avascular necrosis following hip resurfacing in the 1970's. It was also performed in the 1970's as a primary total hip replacement in an attempt to obtain an anatomic range of motion (equal to the opposite normal side). More recently tripolar hip prostheses have been used as revision procedures for recurrent dislocation or occasionally to prevent hip instability in high risk patients.

The design of a mobile bearing hip prosthesis intends to conserve acetabular bone while preserving range of motion and stability by offering movement at both an internal and external articulation. In a well-designed mobile bearing hip prosthesis the motion is shared between the larger outer articulation and the smaller inner articulation. The smaller internal radius will provide much of the motion augmented by movement at the extremes at the large external articulation.

Mobile Bearing Bipolar prostheses were developed in the 1960's to reduce movement between the femoral head and acetabulum by transferring some of the movement to a second articulation between the head and stem. The goal was to reduce acetabular wear and stem loosening. A variety of prostheses were developed such as the Trunnion Bearing Weber and Christiansen Prostheses and, Bateman Single Assembly and Giliberty Bipolar Prostheses.

Using a Tripolar prosthesis requires a higher level or surgical expertise compared to total hip replacement. A deep understanding of the implants and careful placement are required. Also, the implants require intraoperative assembly.

Indications

The intended use of a Tripolar Hip Replacement Includes:

1. Revision of hemiarthroplasty procedures for pain associated with acetabular erosion or migration.
2. Revision of a previous hip implant procedure for recurrent dislocation.
3. Arthritis of the hip; degenerative, post traumatic and inflammatory.
4. At Risk for Dislocation situations which include:
   - (i) Neurologic or muscular disease which impair stability.
   - (ii) Tumor Reconstruction.
   - (iii) Dementia
   - (iv) Post traumatic conditions with loss of the stabilizing trochanters.
   - (v) Sports or Occupations where dislocations would be dangerous.

System Concepts & Description

Principles of Effective Tripolar Hip Replacement Design

There are 7 principles that are important for an effective Tripolar Hip Replacement:

1. Wear. Highly cross linked polyethylene has shown to reduce wear by a factor of 10. Combined with TiN ceramic coating the wear of the articulating surfaces had been reduced below the threshold for prosthetic failure.
2. Positive Eccentricity. This is a key design feature the most successful bipolar implants. This has been used successfully for four decades.
3. Stability and Range of Motion: It is necessary to use a design that provides for a full range of motion and stability.
4. System Flexibility: Since these implants are often used in revision settings is necessary that the bipolar component have compatibility across manufacturers. The capacity of the bipolar to accept all 28 mm heads whether they are metal, ceramic or ceramic coated is important. It is necessary that the bevel of the bipolar head work with the femoral neck of most implants.
5. Ease of Assembly and Disassembly: The Bipolar retaining ring and the 6 finger disassembly tool are important features providing safe and effective component use.
6. Resistance to Component Separation: The system provides 800 lbs. of separation force for disassembly and it has been used without disassembly since 1988.
7. Comparison to Other Systems. The UHR from Stryker and the Self-Centering Bipolar from Depuy both provide positive eccentricity. The Self- Aligning system described here has been offered by several manufacturers for 38 years.

Potential Disadvantages of Dual Mobility Designs

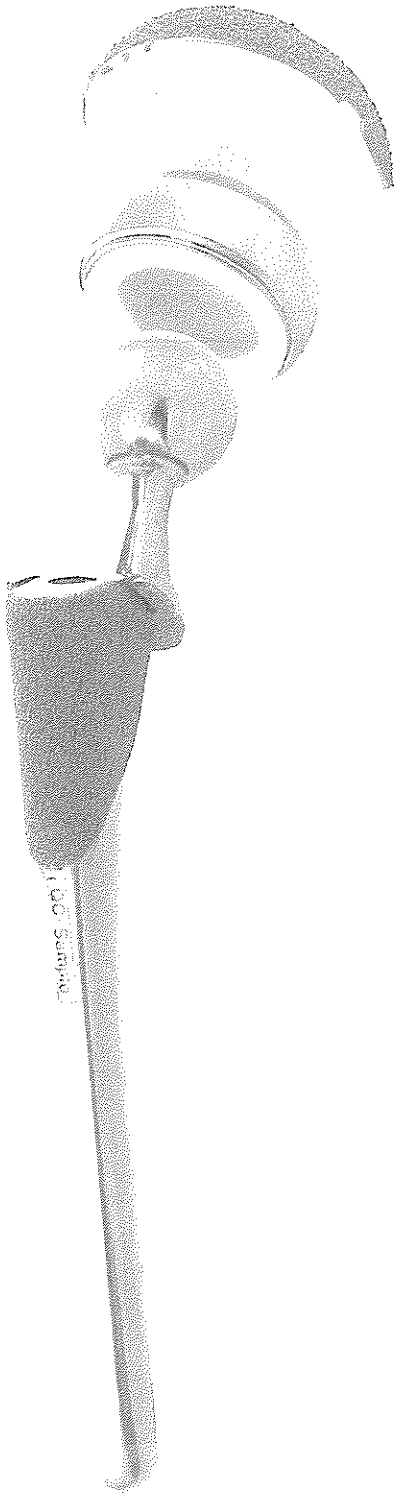
1. Dual Mobility designs have grown significantly in popularity since their first introduction in France in 1976. In these designs a one-piece metal socket is placed in the acetabulum. A large mobile polyethylene head is snap fit on the smaller femoral head component. Adjunctive fixation was either not possible or limited because of the one-piece shell. Also sensitivity to the metal itself is an issue for some patients.
2. Two-piece metal sockets have now been provided but corrosion between the metal liner and the metal backed shell are concerns.
3. The largest concern, however, is intraprosthetic dislocation. This means the femoral head comes out of the polyethylene mobile bearing. This requires revision surgery. Intraprosthetic dislocation is more common in a dual mobility implant as the uncovered large polyethylene bearing can be damaged by rim contact with the metal acetabular shell or at the "throat" area where the femoral neck contacts the polyethylene to drive the motion.
4. There is stress shielding behind the one or two-piece rigid metal acetabular components.
5. Convex polyethylene wears more than concave polyethylene

Acetabular Components

The Acetabular Component is a 2 mm thick (excluding the plasma spray coating) hemispherical metal fixation cup. The spherical fixation surface; provides positioning flexibility, ease of acetabular preparation, and minimal loss of acetabular bone. Further, use of a spherical fixation surface minimizes the generation of tensile and shear stresses at the bone-prosthesis interface under varying loading conditions because part of the spherical surface is always perpendicular to the load vector.

The configuration and positioning of the Acetabular Component approximates the coverage provided by the acetabular cartilage it replaces. The Acetabular Cup is positioned to account for necessary inclination and combined anteversion (rotation) of the hip. Thus, normal head coverage, joint stability, and joint kinematics are provided and impingement between the femur and the cup is limited to what is anatomically required of each individual hip.

The anatomical placement and configuration produces centralization of the cup on the line of action of the peak load vector since the acetabular cartilage is similarly centralized. This centralization provides the most uniform and the best approximation to normal stress distribution in the acetabulum. Anatomical placement produces an orientation of the components specific to the needs and function of the individual anatomy. It is important to keep in mind that each hip is different.

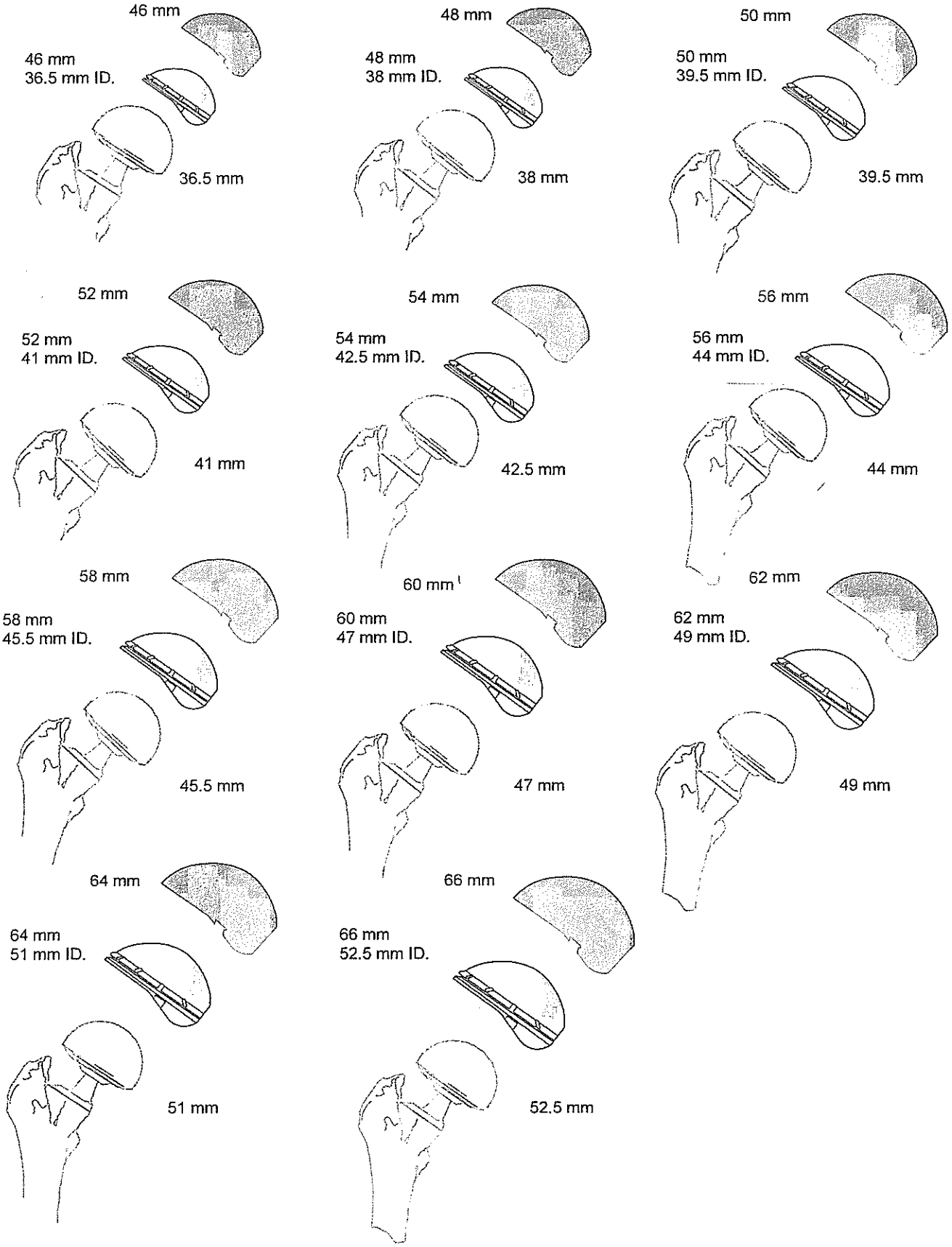


Self-Aligning Bipolar Acetabular Component

The Self -Aligning Bipolar acetabular component inner bearing is made of Polyethylene. It is sterilized in Ethylene Oxide. The polyethylene has a split that runs nearly to the dome. The capture is a stopper ring design. The ring is titanium nitride (TiN) coated. The mouth has a 28 mm capture and it can accept a cobalt chromium, ceramic or ceramic coated femoral head. The face angle at the mouth has a bevel and there is a reduced edge distance to reduce the chance of component separation.

The bipolar head component has a ceramic (Titanium Nitride) coating applied to a Ti6Al4V substrate. This ceramasized metal shell serves as the external and larger articulation. It can only be separated from the underlying polyethylene by a separation tool that employs 6 fingers on the tabs on the ceramic coated metal shell. The Shell and polyethylene inner bearing come assembled and are press fit onto the femoral head. The extraction tool is necessary to remove the bipolar head in case of the need for revision. This bipolar locking mechanism has been in continuous use since 1988.

The wear of the Tripolar ensemble is similar to a conventional total hip replacement. It is less than a Bipolar prosthesis because of the reduced frictional of the acetabular component and it is less than a dual mobility prosthesis as the polyethylene articulates on its concave surface rather than convex.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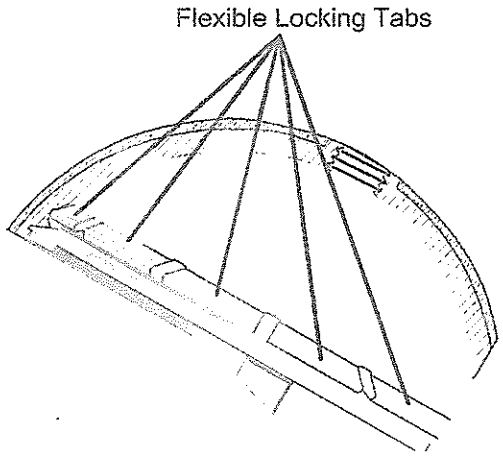
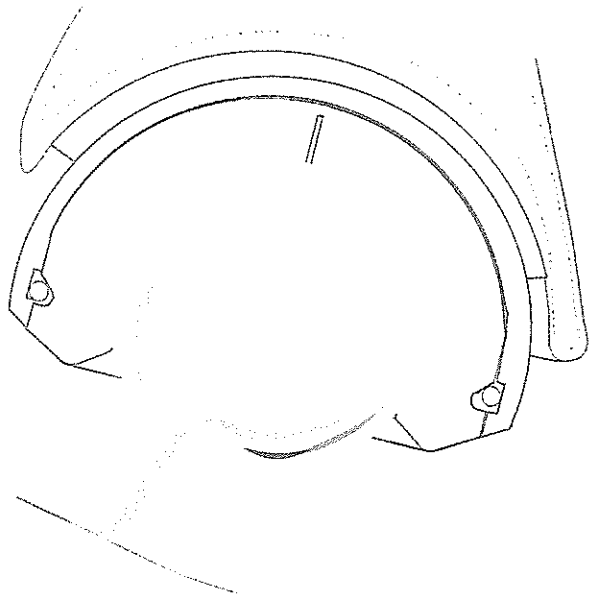
TRIPOLAR ACETABULAR COMPONENT SYSTEM

Reliability of Assembly: Fixed Bearing Stability

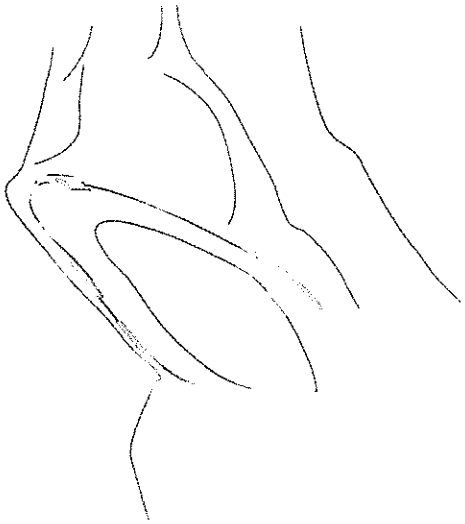


Frictional torque between the femoral head and the fixed bearing insert is resisted by a greater friction between the interior wall of the fixed cup and the outer spherical surface of the bearing insert. To prevent migration of the fixed bearing insert (such migration does occur in the Self-Aligning insert), three anti-rotation keys are used to resist the rotation of the bearing insert relative to the metal cup. Further, these keys help resist micro motion, since they are pressed into the metal cup wall. The keys, particularly the superior key, help align the bearing insert with the metal cup during its installation.



Clinically Proven Fixed Bearing

The Fixed Acetabular Cup and Bearing Insert have evolved from 38 years of development and clinical use. Large, flexible, locking labs on the bearing insert engage a deep groove in the metal cup providing a deep engagement fit resisting separation of the bearing insert. Precision machining of the cup and insert produces a locking fit resisting micro motion of the bearing relative to the metal cup. Such micromotion can produce wear debris at the bearing insert to metal cup interface.



Clinically Proven Bipolar System-Extended to Tripolar

The Self-Aligning Acetabular Components in their current form have been in continuous clinical use since 1988. Several manufacturers use an identical system without the TiN coating.

The metal retaining ring provides a strong, dimensionally stable, connection between the metal cup and bearing insert. This connection is capable of resisting more than 800 lbs of tensile separation force. The large amount of engagement between the bearing insert and the femoral head provides a separation strength in excess of 500 lbs.

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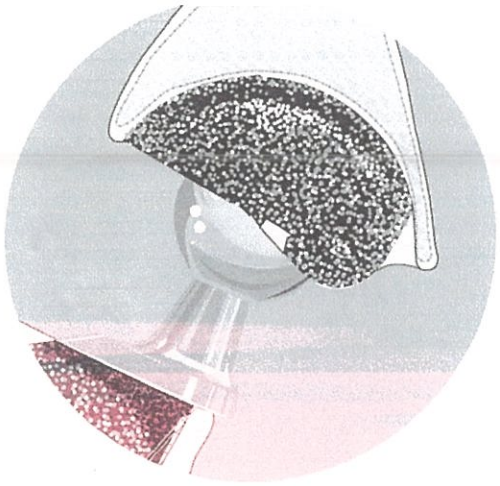
TRIPOLAR ACETABULAR COMPONENT SYSTEM

TiN Ceramic Surface Coating



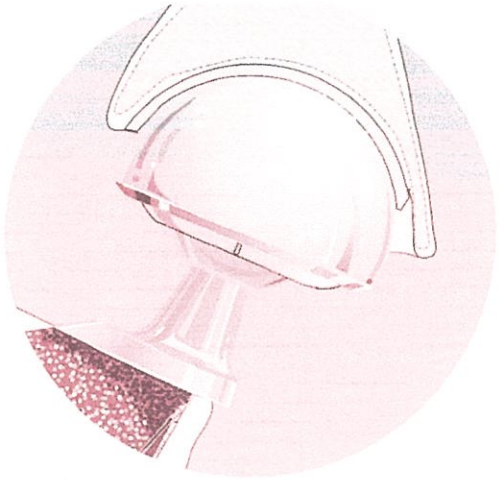
Description

The titanium metal is coated with an inert, highly adherent, near diamond hard titanium nitride (TiN) ceramic coating about 10 microns thick. This coating reduces wear by more than two thirds and friction by about one-half compared to Co-Cr alloy heads when articulated against a polyethylene bearing surface. The extreme hardness of the TiN ceramic coating is attested to by its wide use on tools for cutting steel and other metals. TiN coatings are now also used on orthopedic implants to successfully address metal sensitivity. The TiN film is produced by a series of processes that carefully monitor and control pre-coating surface preparation, the coating process, and the post-coating polishing. These procedures guarantee the film adherence and the reductions in wear and friction observed during extensive testing.

The coatings are extremely adherent on a properly prepared, contaminant free, substrate. Such adhesion results from an ionic (atomic) bond between the film and the substrate. When a TiN ceramic film is applied to titanium alloy, the film to substrate interface is not susceptible to corrosion, and thus, corrosion delamination. In fact, a titanium coating is applied to steel industrial parts to be coated with TiN for applications requiring corrosion resistance.

Substantial reductions in wear and friction against polyethylene result from the extreme hardness of the TiN ceramic film. This film is substantially harder than the delta ceramic used for femoral heads from most manufacturers. To obtain these improvements, however, the TiN film must be polished. The polishing process allows for the production of a substantially smoother surface than can be obtained on softer materials. It is this substantial increase in smoothness that results in a significant decrease in friction and wear. Further, the extreme hardness of TiN ceramic results in a decrease in the rate of degradation of the polished articular surface, thus producing a progressive resistance to wear.

The first FDA cleared orthopedic use of TiN coating was for the O.E.C. Self-Aligning Prosthesis (this implant). This landmark 510K was obtained in 1988 at the direction of Nik Nikolaev, President of Protek USA. All TiN orthopedic uses trace their legacy to this initial use. Mr. Nikolaev was a pioneer in implant development for Depuy, Protek, Orthomet and Wright Medical Technology. TiN and Titanium Niobium are now extensively used in total knee, total hip, and total shoulder replacement. Hip and shoulder resurfacing prostheses using TiN have been used since 1989.



Enhanced Biocompatibility

Titanium alloy and TiN coating are more biocompatible than Co-Cr alloy whose major components can generate metal sensitivity reactions in some patients. TiN ceramic is inert in vivo and it shields the surface of the implant, particularly the porous coated region with its high surface area, against metal ion release. As a result, titanium acetabular cups which are the most biologically compatible of osseointegration and reduced stress shielding can be used.

Reduced Acetabular Erosion and Metallic Debris

TiN coating using Self-Aligning and femoral head components because their smoothness, hardness and biocompatibility minimize the release of potentially harmful metallic debris which may result from wear.

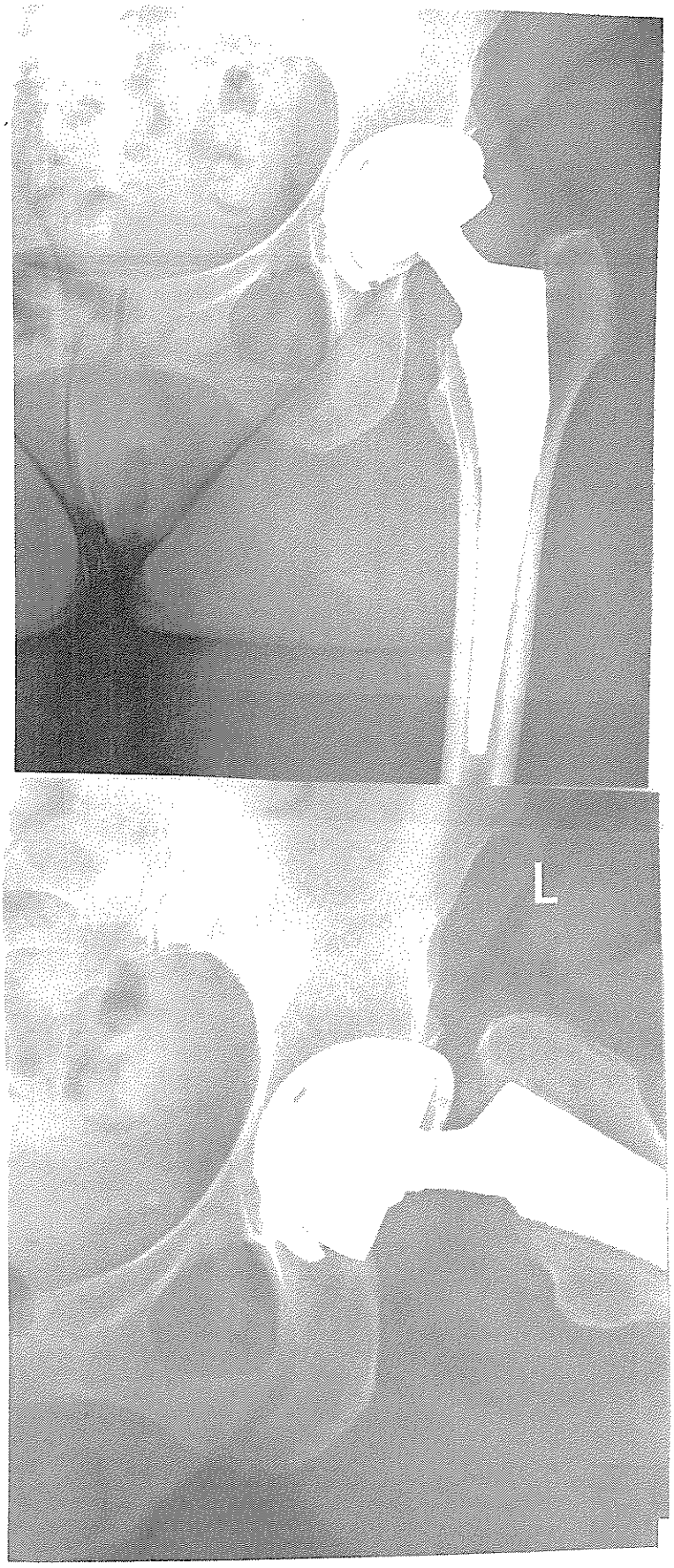
Self-Aligning Acetabular Component
Maximum Internal Range of Motion with Superior Dislocation Resistance

Positive eccentricity generates a restoring torque which tends to align the axis of the Acetabular Cup with the direction of the peak load vector which when used with the Femoral Stem is also along the axis of the stem neck. This alignment minimizes the undesirable motion between the Bipolar Acetabular Cup and articular cartilage or the liner of the acetabular component for the Tripolar Application

The ceramic TiN coating reduces friction at the inner articulation interface further reducing motion between the Acetabular Cup and articular cartilage or acetabular liner of the Tripolar

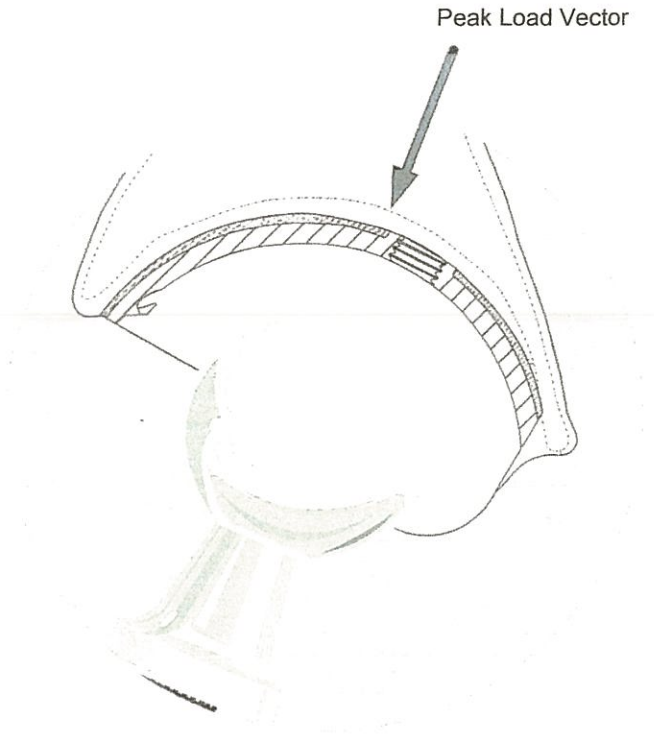
Wear in many bipolar prostheses occurs primarily at the joint surface between the femoral head and the polyethylene of the bipolar. Ideally the motion is shared between this bearing surfaces and the native acetabular articular cartilage or the liner of the Tripolar. The Self-Aligning Prosthesis demonstrates this by taking films in the maximum abduction position and comparing to the neutral position.

Wear occurs at three surfaces in a Tripolar Prosthesis (1) The acetabular liner-femoral head articulation (2) The dome of bipolar polyethylene-bipolar TiN articulation surface and (3) The rim of the bipolar-femoral neck junction The overall wear is modest and compatible with a lifetime of use under the most active conditions. The greatest wear is at the rim of the bipolar. The wear is less than occurs with the popular dual mobility implants



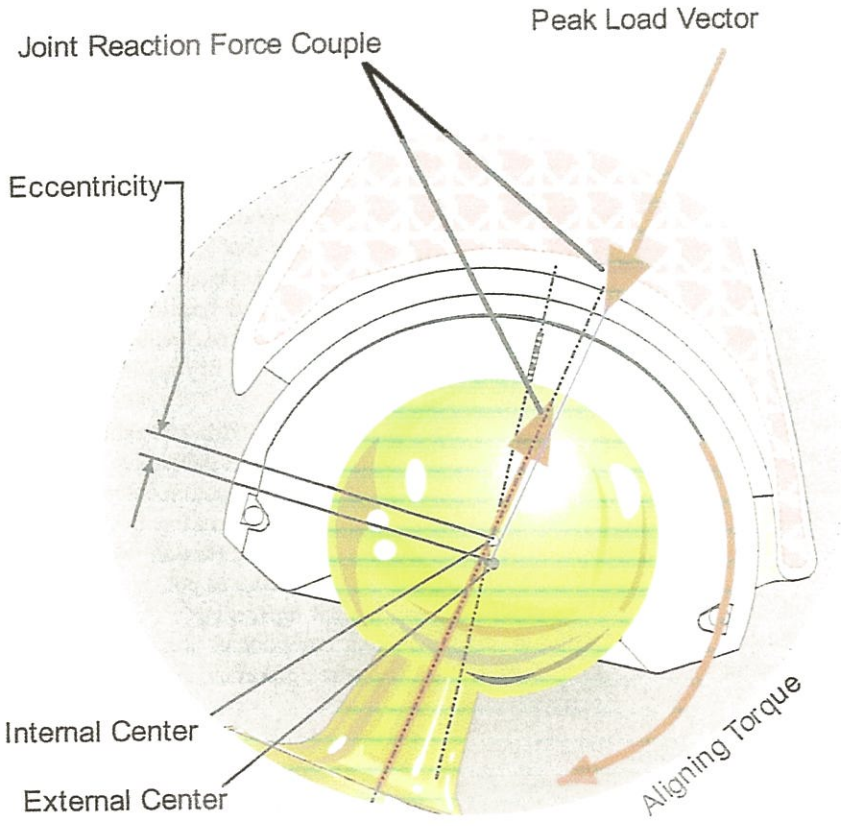
TRIPOLAR ACETABULAR COMPONENT SYSTEM

Alignment with Peak Load Vector



Fixed Cup Position

The fixed acetabular cup is designed to be implanted with its face at 30-50^0 from the horizontal and in 10-30° of anteversion. At this orientation, it is aligned with the Peak Load Vector resulting from normal activity. Such alignment produces greater uniformity of compressive stress at the prosthesis to bone interface providing more favorable conditions for establishing and maintaining fixation. In particular, undesirable tensile stresses at this interface resulting from tipping loads are minimized by such alignment.



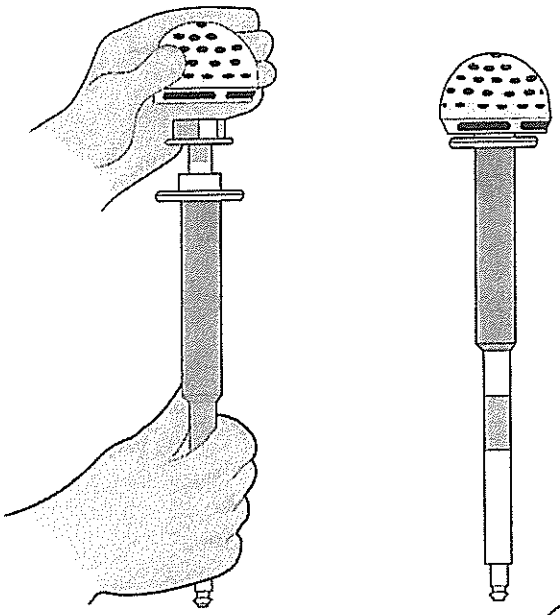
Bipolar Cup Position

The Self-Aligning Acetabular Component is kept aligned with the Peak Load Vector by the effect of the Positive Eccentricity built into the bearing insert. The outside spherical surface of the bearing is made eccentric to the inside surface by an amount given by the equations. Such eccentricity produces a small force couple when the cup is not aligned with a joint load vector. Since the effect is greatest when a misalignment exists with the Peak Load Vector, the cup tends to align itself with this vector. Such alignment ensures that the cup edge does not wipe across the articular cartilage when used as bipolar or the polyethylene liner when used as a tripolar and that contact occurs with the spherical portion of the cup.

Improved Motion with Any Femoral Stem

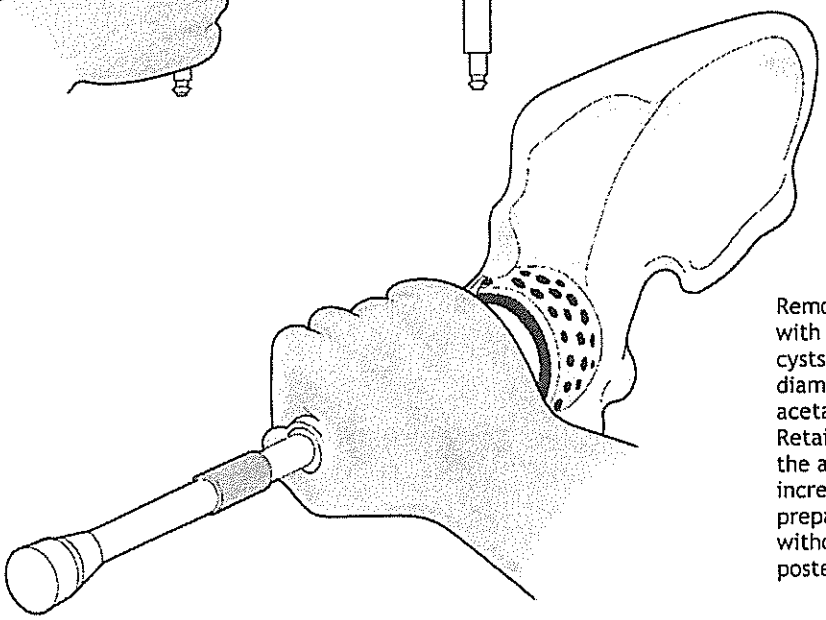
The Self-Aligning Bipolar can be used with any suitable Femoral Stem. The design of the femoral neck can be a determinant of movement of the bipolar. Wear at this impinging surface is much less than dual mobility systems and compatible with a lifetime of use.

Acetabular Preparation

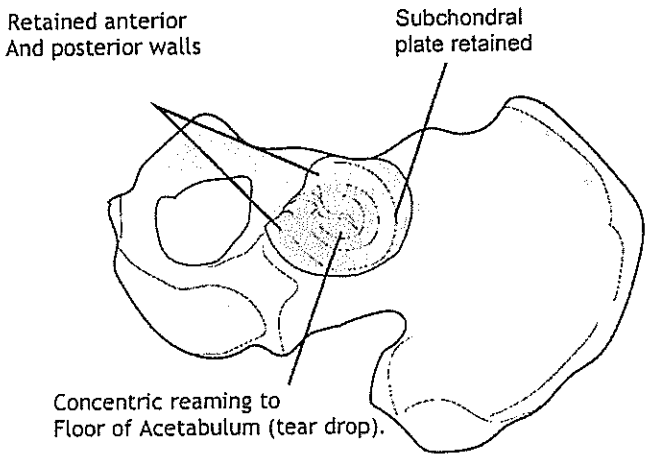


Acetabular Preparation

Assemble the correct size **acetabular reamer head** and handle. Retraction of the Reamer Sleeve allows removal of the **reamer head.** Engagement of the Reamer Sleeve prevents the reamer head from disconnecting from the **handle.**

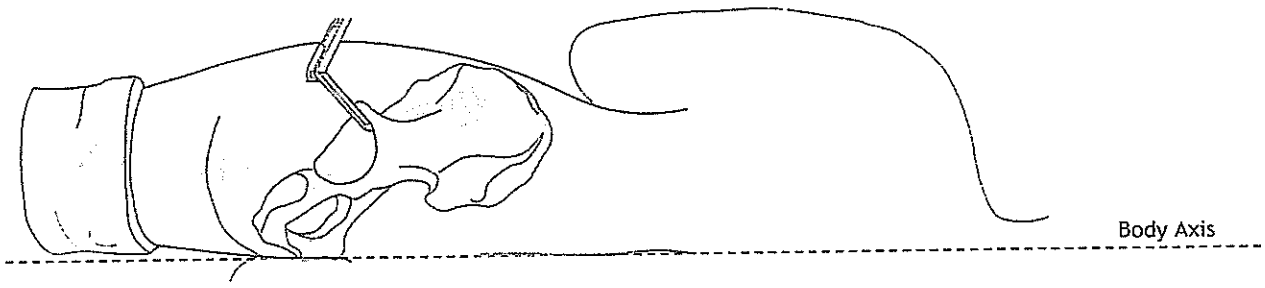


Remove the soft tissue contents of the acetabulum with curettes. Assess the bony walls for defects and cysts. Remove all loose tissue. Use the smallest diameter reamer that fits snugly to deepen the acetabulum to the floor of the acetabular fossa. Retain the subchondral plate in the superior region of the acetabular dome. Widen the acetabulum with increasing diameter reamers until a concentric preparation meets the floor of the acetabular fossa without removing the outer table of the anterior or posterior walls.



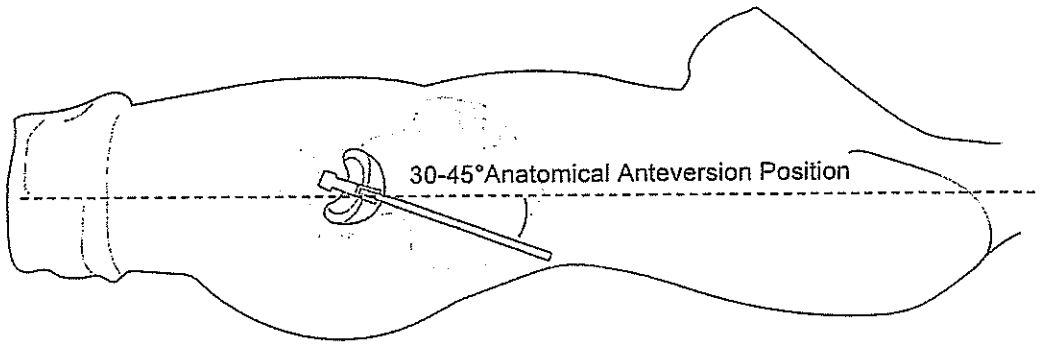
Note: Continuous downward pressure on the reamer sleeve will prevent removal of the subchondral plate in the superior acetabular dome during the reaming process.

Acetabular Trial Fit and Component Selection



Acetabular Component Trial Fit

Assemble the acetabular sizing trial and its handle. The trial represents the dimension of the implant with porous coating, and are identical to the implant of that size. Place the trial into the prepared acetabulum and check for bony fit, coverage, and orientation. The fit should be tight with no side play or tendency to rotate against resistance. The Trial should be positioned an atomically in anteversion with the handle parallel to the body axis (usually 30° to 45°).

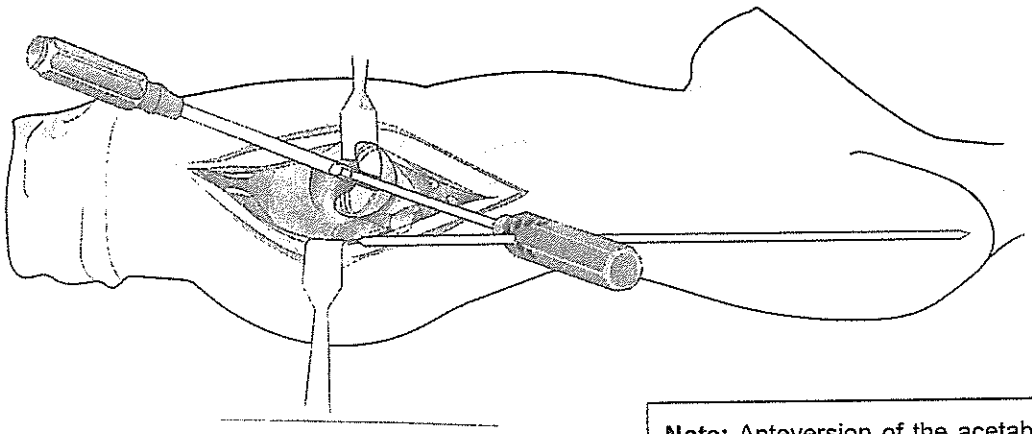


Acetabular Component Selection

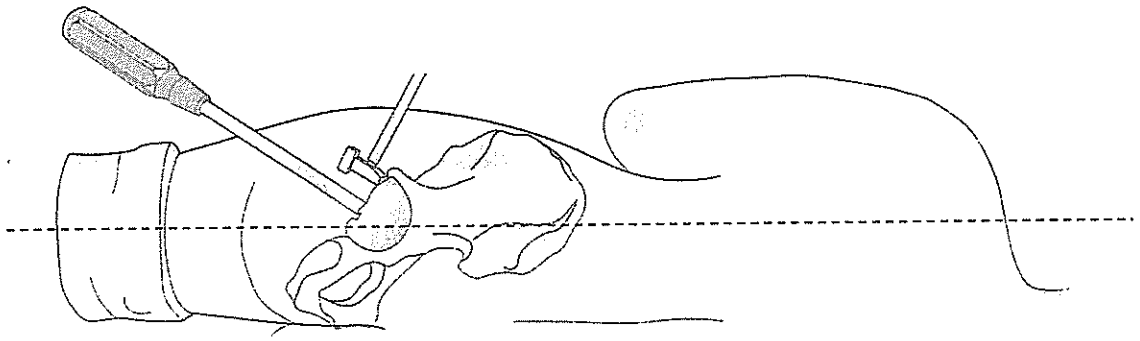
Press-fit application requires an acetabular cup size of 2 mm larger than the reamed cavity in hard bone such as osteoarthritis and 3 mm larger than the reamed cavity in soft or osteoporotic bone such as in rheumatoid arthritis. Thus, the final acetabular component size will be either 2 or 3 mm larger than the reamed cavity depending upon the bone quality.

Acetabular Component Placement

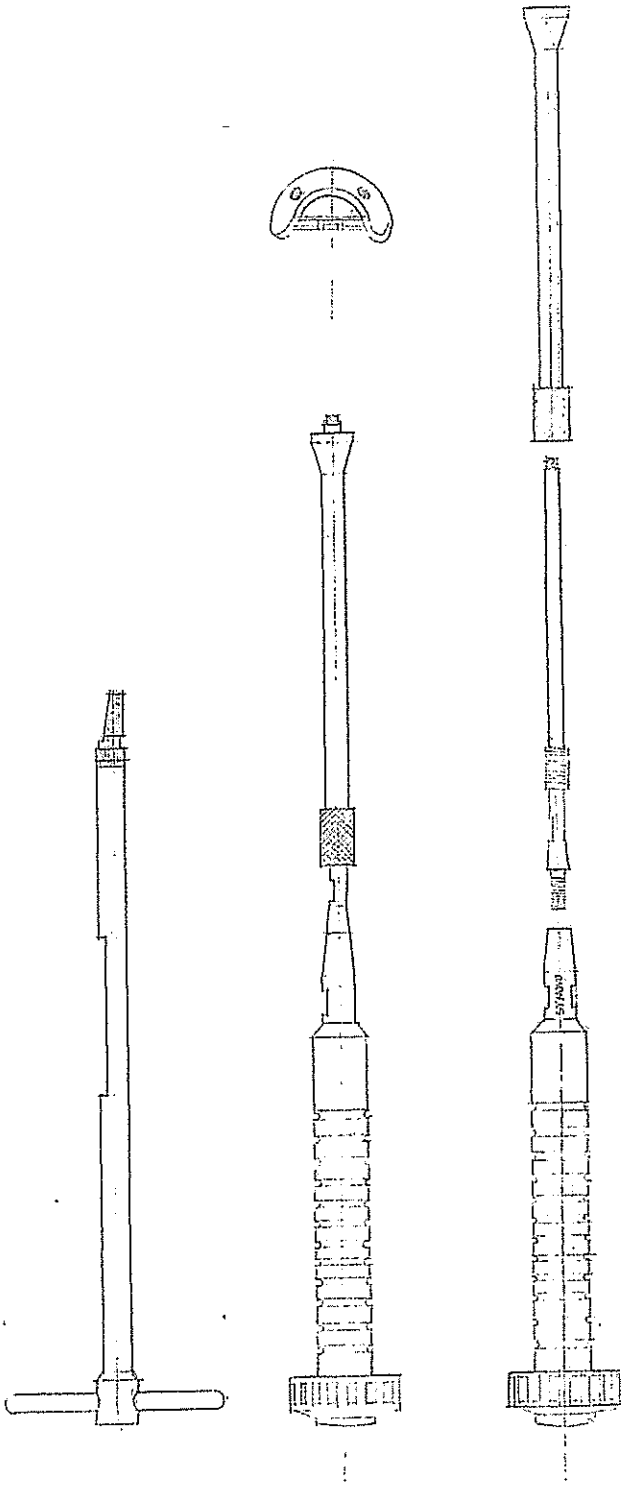
Insert the Acetabular Component into the same version position as determined during trial reduction. Bring the alignment rod of the acetabular cup positioner in line with the body axis to allow a 30° face angle from the horizontal axis (line drawn between the ASIS).



Note: Anteversion of the acetabular cup should be referenced from and recessed inside the bony acetabular borders, except superiorly and posteriorly where the cup may extend slightly, improving dislocation resistance at 90° of flexion and 45° of internal rotation. From the posterior approach the anteversion angle may appear to be 30° to 45° because of pelvic tilt.



Acetabular Component Implantation



Acetabular Component Placement

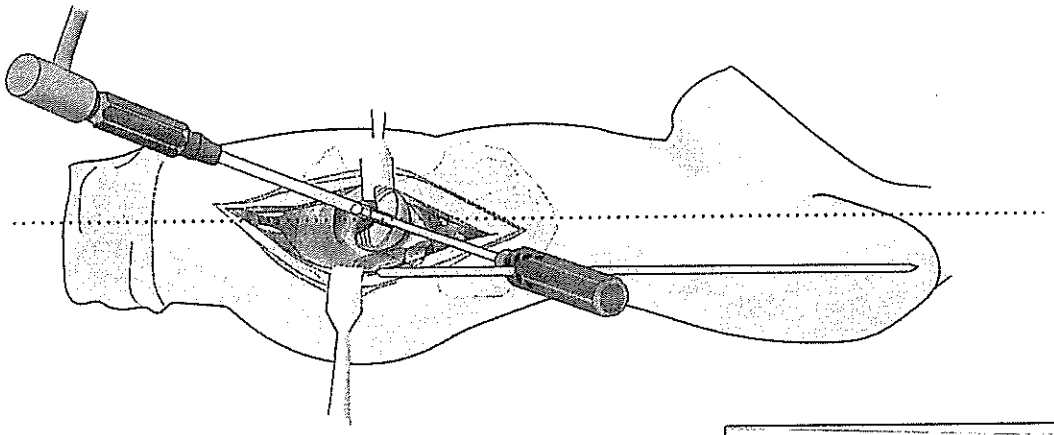
Assemble the properly sized Acetabular Component onto the acetabular cup positioner. Thread the acetabular cup holder/impactor into the central hole in the acetabular component.

Impact the polyethylene into the shell using the appropriate specific sized polyethylene impactor. Use the black tip polyethylene impactor for final seating

Acetabular Component Implantation (cont'd)

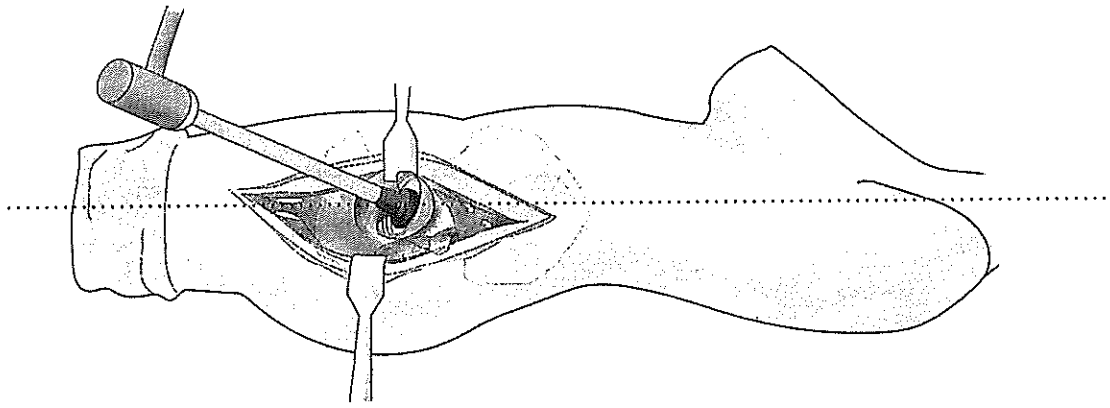
Acetabular Component Impaction

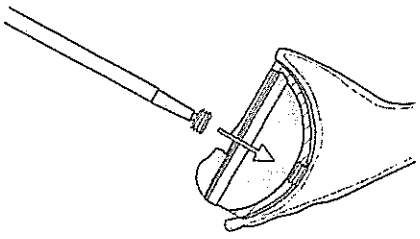
Impact the cup into the prepared acetabulum, using the acetabular cup holder/ impactor. Once this cup is fully seated, remove the acetabular cup positioner and unscrew the acetabular cup holder/ impactor.



Check the depth of seating of the cup with a clamp through the central hole. If incompletely seated, use the spherical Acetabular Cup Impactor to fully seat the metallic cup.

Note: Fine tuning of acetabular cup placement or version angles can be performed by impacting the rim of the cup with a bone tamp (Square Moe Impactor is best). Take care not to damage the keyways.

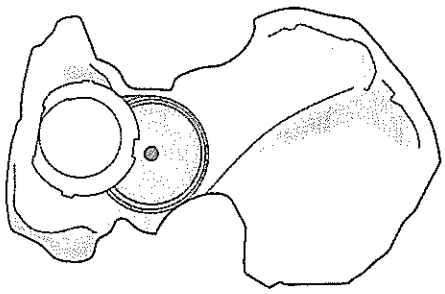




Optional:

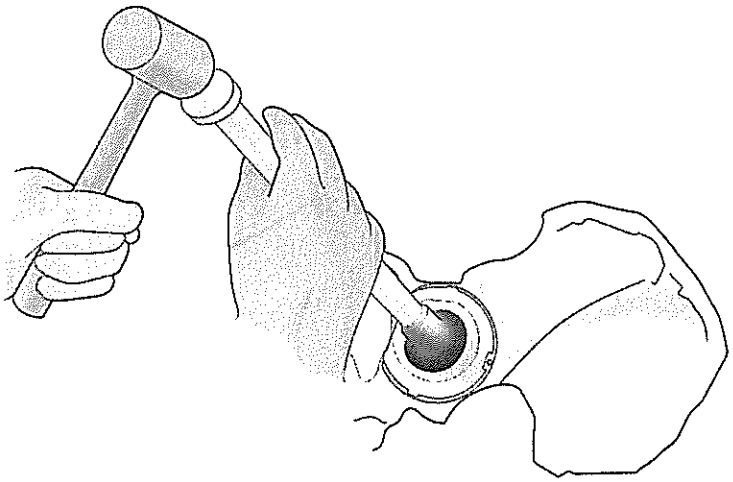
Once the proper position has been achieved, fill the central hole of the cup with the acetabular cup plug.

Bearing Insertion

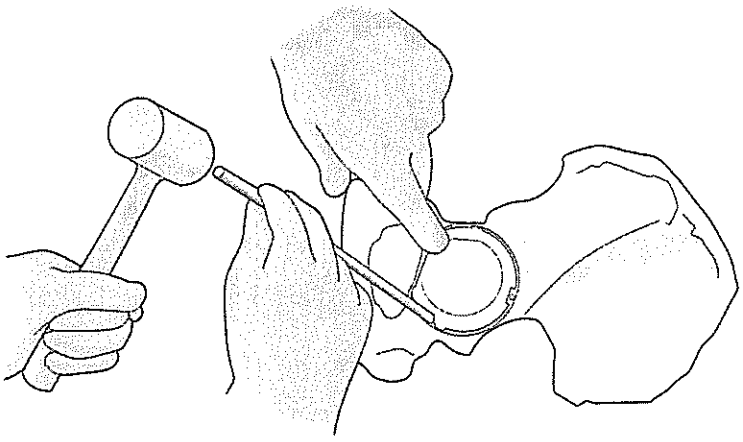


Inserting the Acetabular Bearing

Rotate the highly cross-linked UHMWPe Acetabular Bearing to engage the superior surface keyway in the Acetabular Component. Apply firm digital pressure and engage the two lateral bearing tabs in the slots in the metal cup.

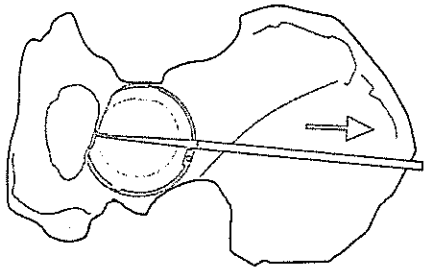


Impact the bearing into the cup using the acetabular cup impactor.



To improve seating, impact the two lateral bearing tabs into the mating slots on the metallic cup using the bearing impactor Rod. The bearing impactor rod is used to firmly seat the lateral bearing tabs until the rim of the polyethylene lies flush with the rim of the metal cup.

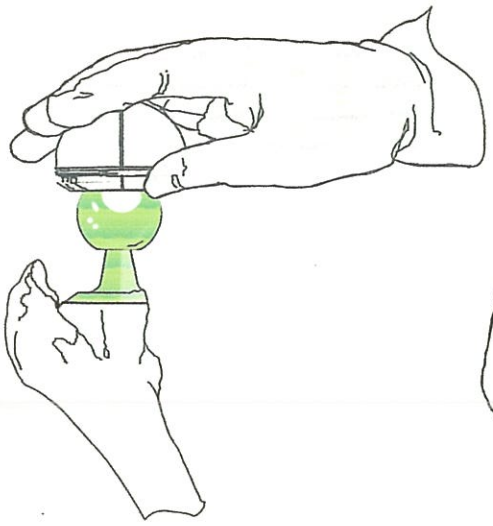
Note: A second blunt rod or an assistant's digital pressure may be used to stabilize one side of the polyethylene cup, while the opposite lateral bearing tab is seated into the slot.



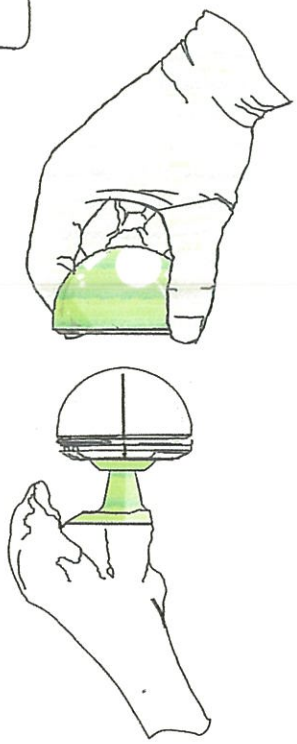
Checking the Acetabular Bearing

Hook the inferior surface of the Acetabular Bearing with the bearing hook and pull upward to check the stability of the seated bearing. If the bearing comes free, repeat the seating process or use a new bearing if any instability exists.

Self-Aligning Acetabular Component Insertion



1. Push the Self-Aligning Acetabular Bearing onto the Femoral Head.



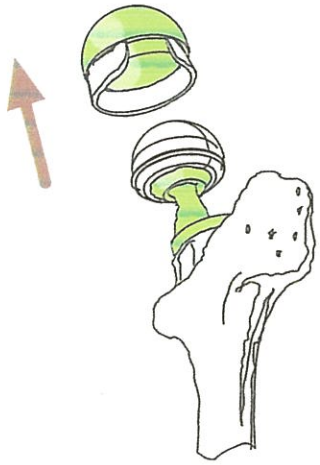
2. Push the Self-Aligning Acetabular Cup onto the Bearing until the metallic snap ring on the bearing engages the groove in the Cup. Be sure to align the metal cup with the metal ring evenly before seating the metal shell.

3. Pull on the assembled cup to be certain the snap ring is engaged.

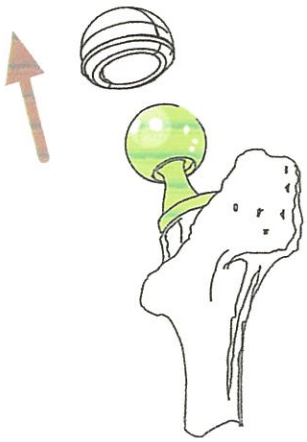
Self-Aligning Acetabular Component Removal

1. Insert the teeth of the Extrator Ring into the recesses in the cup.

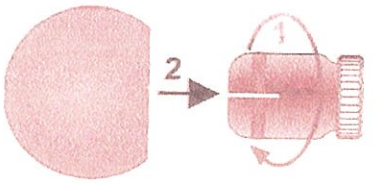
2. Pull the Cup and Ring together off the Bearing.



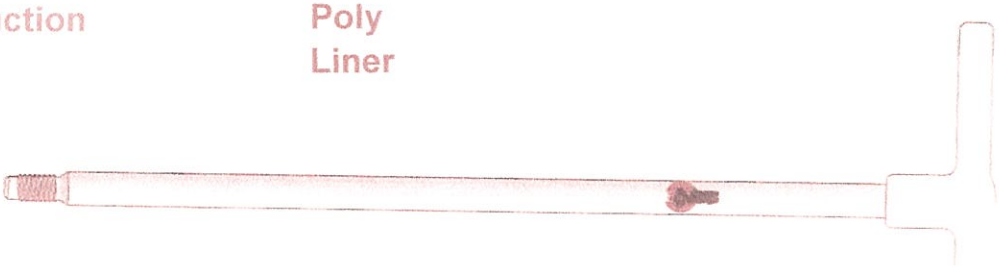
3. Pull the Bearing off the Femoral Head.



Trial Fit and Reduction



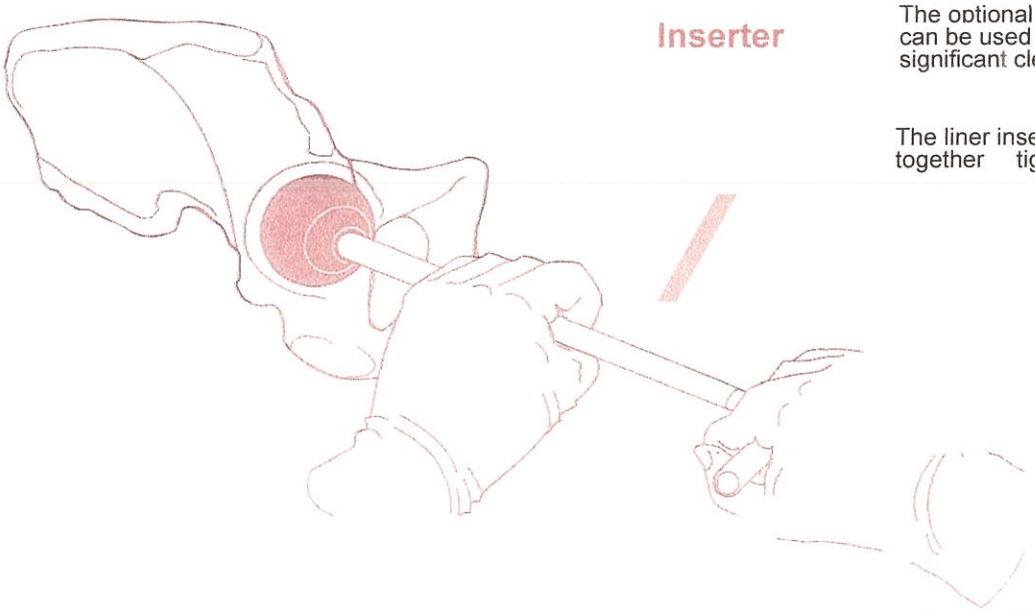
Poly Liner

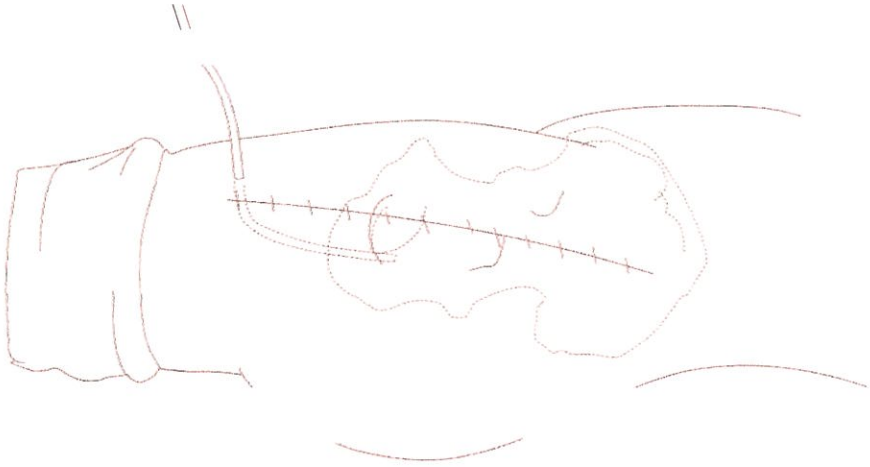


Inserter

The optional polyethylene liner inserter can be used as the liners fit snugly and without significant clearance.

The liner inserter requires assembly and fits together tightly.





Final Reduction and Evaluation

Carefully reduce the head of the Femoral Component into the Acetabular Component, or acetabulum, by traction and internal rotation. Flex the hip to 90° and record the internal and external rotation available. Any soft tissue or bony impingement to motion should be corrected at this time.

Note: Internal rotation of 45° and external rotation of *30°* at 90° of hip flexion with neutral abduction should be possible without dislocation of components.

Postoperative Care

Apply an occlusive silver dressing and leave in place up to 2 weeks. It is anticipated the procedure is performed as an outpatient. Immediate weight bearing is encourage and the patient and care giver are instructed in the proper care. Progressive ambulation with weight bearing to tolerance should also begin on the operative day. Progressive abduction, antigravity resistive exercises should begin and continue. A walker, crutches or walking poles are continued until ambulation without a limp is achieved. External support is continued until a normal gait without an abductor lurch is achieved. Hip flexion beyond 90° and all usual, non-impact activities may be resumed after 6 weeks, when capsular reformation has been achieved and normal gait has been restored.