

PINNAACLE®

ACETABULAR CUP SYSTEM



▶ FIXATION FIRST

▶ ADVANCED MODULARITY
VIP TAPER

▶ MANAGING DISLOCATION
OPTIMIZING RANGE
OF MOTION AND
STABILITY

▶ WEAR REDUCTION

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DESIGN MISSION AND VISION



In 1982 I implanted my first porous-coated cup, the original AML®. In 1986 I helped DePuy design their first modular porous-coated cup and in 1990 their second generation modular cup, Duraloc®. All three have provided very durable fixation. Now, potentially better bearing surfaces have become available. The Pinnacle Acetabular Cup System, our third generation modular design, has been developed to take advantage of these new bearing surfaces.

THE PINNACLE CUP DESIGN TEAM'S OBJECTIVE WAS:

To create an acetabular cup system designed to accommodate multiple advanced bearings and enable surgical alternatives without compromise.

I want to thank my fellow physicians on the design team: Drs. William Barrett, Daniel Berry, Gregory Brick, John Callaghan, Thomas Fehring, William Griffin and Thomas Schmalzried. All of us have helped the engineers at DePuy develop what I think is the most sophisticated acetabular cup system currently available.

Sincerely,

Dr. Charles A. Engh



PINNACLE SURGEON CONSULTANT DESIGN TEAM

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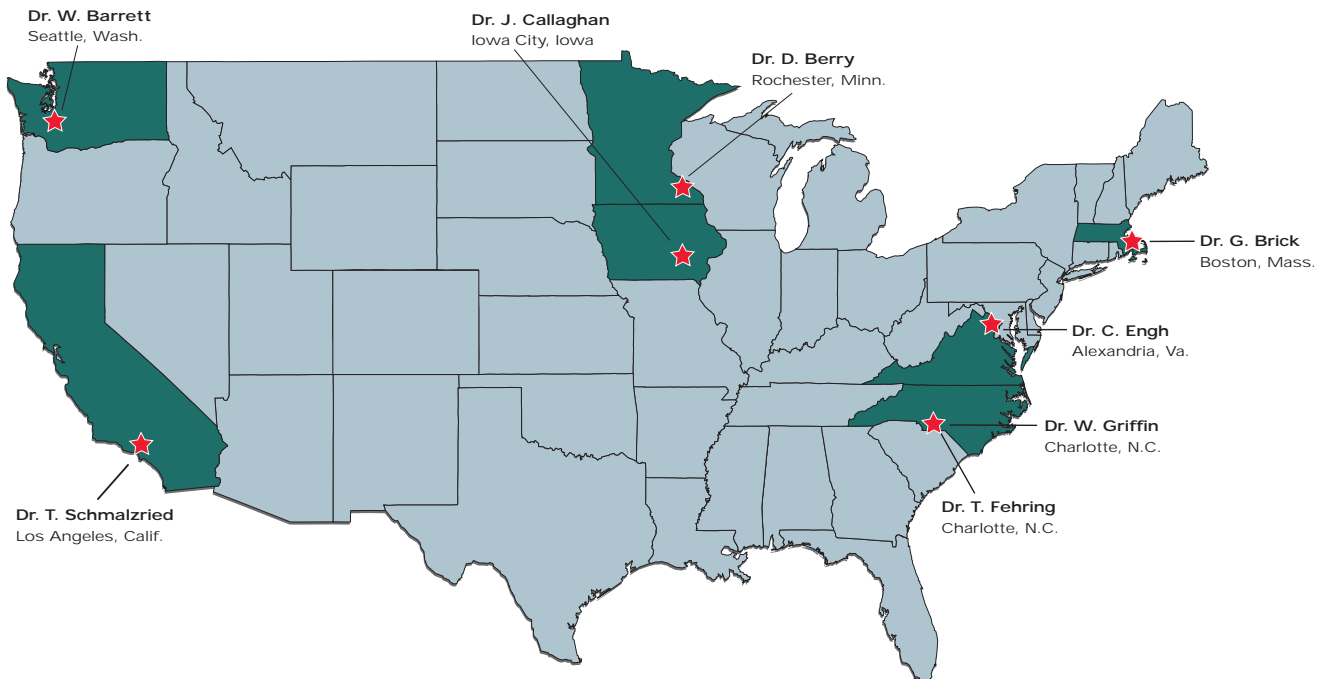
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FOUNDATION FOR CLINICAL SUCCESS

PREOPERATIVE PLANNING

Preoperative planning is essential for the optimal prosthetic reconstruction of the hip joint. The Pinnacle templates enhance preoperative planning by providing all shell profiles with the neutral and lateralized head centers identified.

INSTRUMENTATION

Executing the preoperative plan requires exact surgical technique and precise surgical instrumentation. The Quickset® Grater and Screw Instrumentation Systems, combined with the Pinnacle insertion and trialing instrumentation, are designed to function in concert for maximum efficiency and precision.

FIXATION

Without initial and long-term component fixation, a surgeon's efforts to restore joint function are lost. With the Pinnacle shell, fixation is achieved through 180 degrees of Porocoat® Porous Coating. Unchanged in structure since its 1977 introduction, Porocoat Porous Coating has established a clinical success record of more than 20 years.

RESTORATION OF JOINT BIOMECHANICS

Proper restoration of joint biomechanics positively impacts clinical outcomes, reduces wear and enhances function. Biomechanical restoration involves both the acetabular and femoral sides of joint reconstruction. The Pinnacle system trials, implants and liner alternatives provide the surgeon maximum flexibility to work with virtually any DePuy femoral component and facilitate biomechanical restoration.

WEAR REDUCTION

The Pinnacle system's microstability, congruency at the polyethylene liner/shell interface and bearing surface alternatives were developed to minimize wear. Polyethylene remains the most frequently used bearing material in total hip arthroplasty. The Pinnacle shell combines an optimal shell/polyethylene liner congruency to help minimize micromotion with standard polyethylene and Marathon® Cross-linked Polyethylene liners. With the improved wear resistance of Marathon polyethylene, larger head diameters up to 36 mm can be used to improve functional range of motion and reduce the risk of dislocation, while maintaining adequate thickness of the acetabular liner.

The Pinnacle Acetabular Cup System's Ultamet® metal insert is manufactured from forged high-carbon wrought alloy. Precision controlled manufacturing of the bearing surfaces results in specially engineered articular surface clearances. Sophisticated manufacturing and advanced grinding and polishing techniques enable Ultamet metal inserts to achieve a very low surface roughness. All of these factors help contribute to exceptionally low wear rates.

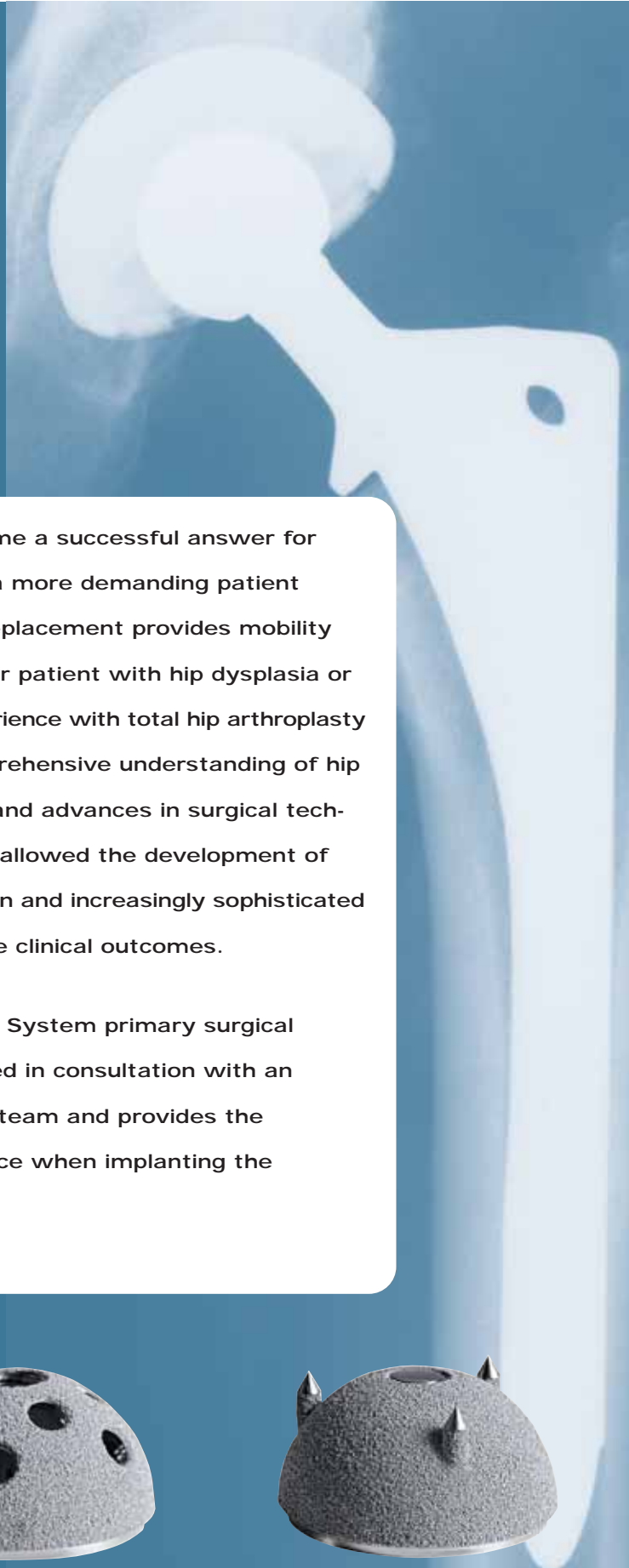
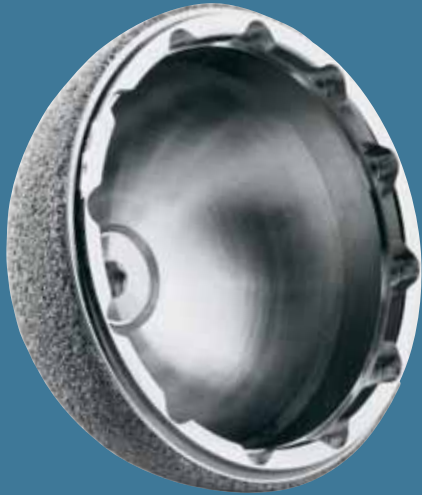


Pinnacle cup with
28 mm ID
Marathon liner

Pinnacle cup with
36 mm Ultamet
Metal-On-Metal
Articulation

SURGICAL TECHNIQUE

INTRODUCTION



Hip reconstruction has become a successful answer for degenerative hip disease in a more demanding patient population. In addition, hip replacement provides mobility and pain relief to the younger patient with hip dysplasia or post-traumatic arthritis. Experience with total hip arthroplasty has resulted in a more comprehensive understanding of hip anatomy and biomechanics and advances in surgical technique. These advances have allowed the development of more efficient instrumentation and increasingly sophisticated implant designs that enhance clinical outcomes.

The Pinnacle Acetabular Cup System primary surgical technique has been developed in consultation with an experienced surgeon design team and provides the surgeon with general guidance when implanting the Pinnacle acetabular cup.



TEMPLATING AND PREOPERATIVE PLANNING

The primary goal of total hip arthroplasty is the anatomic reconstruction of the hip joint, resulting in favorable prosthetic joint load and function. Mechanically, the goals are to create a stable articulation with an optimized range of motion, restore biomechanics for muscular efficiency and equalize limb lengths. Meeting these goals begins with a thorough roentgenographic analysis of the hip with comparison to the contralateral side in anteroposterior (A/P) and lateral projections. The desired magnification for all imaging should be 20 percent, which corresponds to the templates provided for the Pinnacle system. Magnification markers taped to the patient's leg at the level of the trochanter will assist in determining actual magnification.

For the A/P projection, place both extremities in 15 degrees of internal rotation to position the head and neck parallel to the coronal plane. Center the beam on the symphysis pubis and ensure the proximal femoral shaft is included in the radiograph. The radiographs should clearly demonstrate the acetabular configuration and the endosteal and periosteal contours of the femoral head, neck and proximal femur.

Frequently, the affected hip is fixed in external rotation, which leads one to underestimate the amount of offset present. In this situation it may be helpful to template the normal hip. Take a Lowenstein lateral with the patient on his/her side, and the trochanter, ankle and knee on the table. Alternately, take a Johnson's lateral for a detailed examination of the anatomic version and anterior osteophytes. Take into consideration any anatomical anomaly, dysplasia, previous fracture or leg length discrepancy.

The Pinnacle templates are oriented at 45 degrees and allow measurement of any hip that can be accommodated by Pinnacle Acetabular Cup System primary components (48-66 mm). Using the A/P radiograph, position the template 35-45 degrees to the interteardrop or interischial line so that the inferomedial aspect of the cup abuts the teardrop and the superior-lateral cup is not excessively uncovered (FIGURES 1a and 1b).

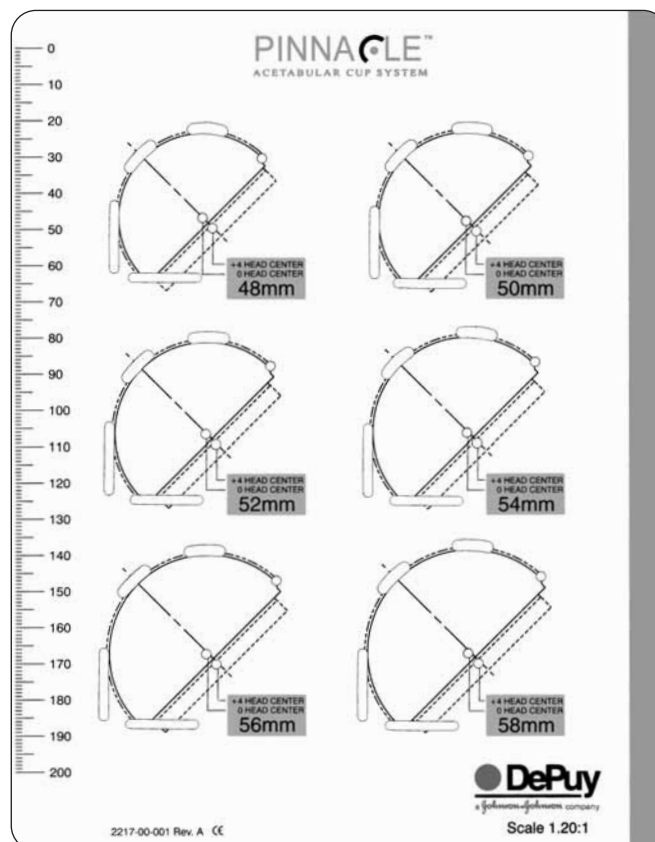
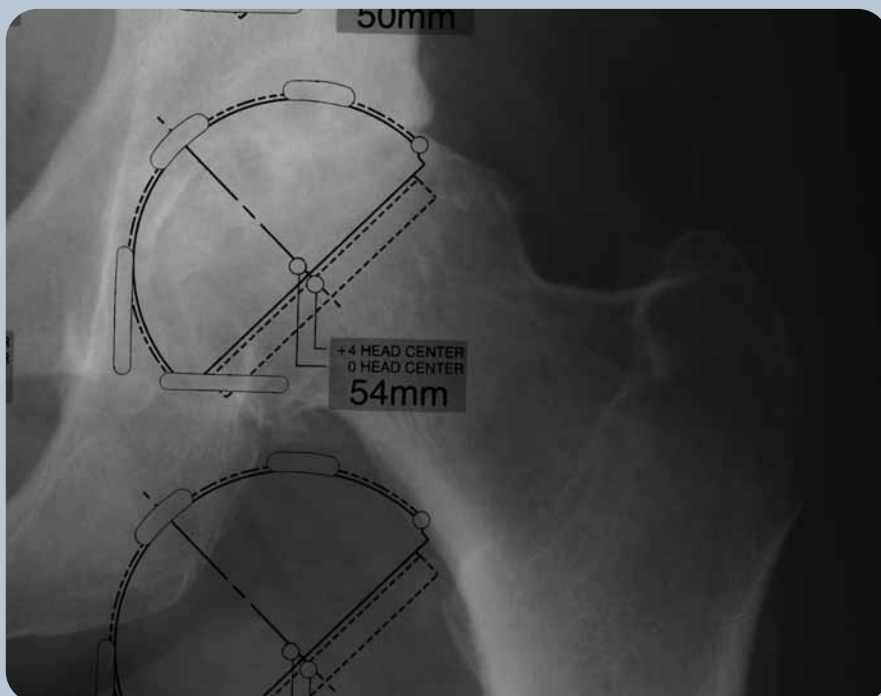


FIGURE 1a



Acetabulum with good lateral coverage

FIGURE 1b



Properly positioned acetabular template

ANTEROLATERAL SURGICAL APPROACH

Use the approach with which you are most familiar and achieve the best surgical result. The Pinnacle Acetabular Cup System instrumentation was designed to accommodate all surgical approaches.

For the anterolateral approach, place the patient in the lateral decubitus position and execute a skin incision that extends from distal to proximal, centered over the anterior aspect of the femur, continuing over the greater trochanter tip (FIGURE 2).

The iliotibial band is split under the skin incision, extending proximally into the gluteus maximus or in between the maximus and the tensor fascia lata muscles (FIGURE 3).

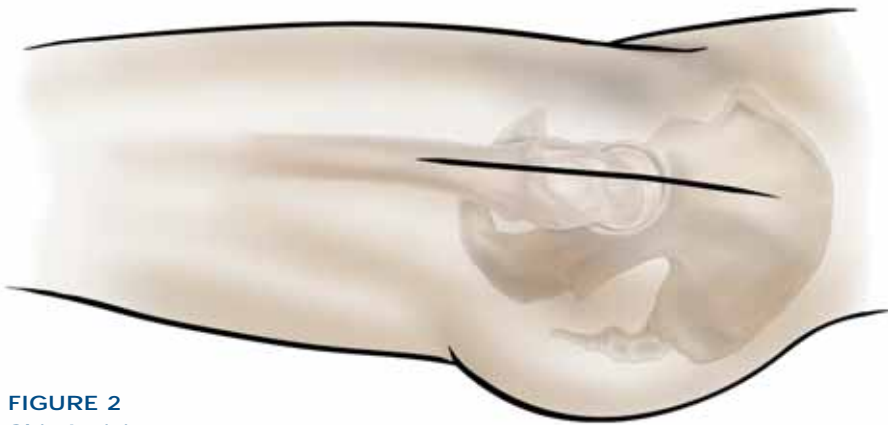


FIGURE 2
Skin Incision

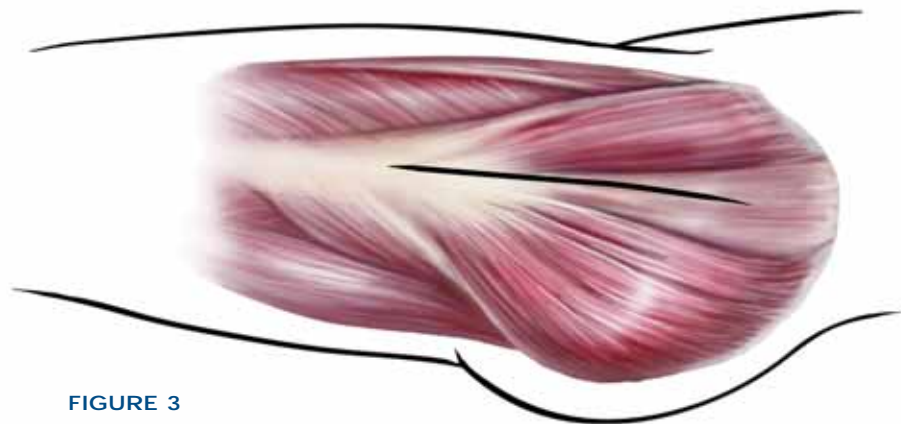


FIGURE 3
Fascial Incision

Palpate the anterior and posterior borders of the gluteus medius. The gluteus medius is split from the trochanter, parallel to its fibers, releasing the anterior $\frac{1}{2}$ to $\frac{1}{3}$ of the muscle (FIGURE 4).

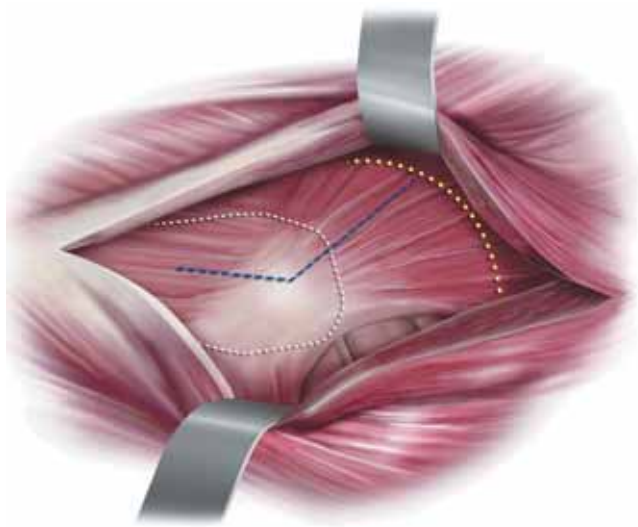


FIGURE 4
Gluteus Medius Split

The gluteus medius should not be split more than 4 cm from the tip of the greater trochanter. Care must be taken to ensure the inferior branch of the superior gluteal nerve is not damaged. The gluteus minimus is exposed and released either with or separate from the gluteus medius (FIGURE 5). Flexion and external rotation of the leg facilitates exposure of the hip capsule, which is incised or excised depending on surgeon preference.

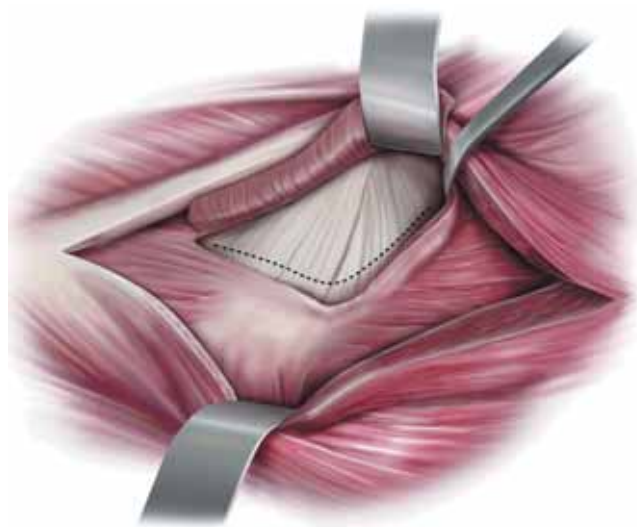


FIGURE 5
Capsulotomy/Capsulectomy

ANTEROLATERAL SURGICAL APPROACH

Dislocate the hip with gentle adduction, external rotation and flexion. The patient's leg is now across the contralateral leg and the foot is placed in a sterile pouch (FIGURE 6). If dislocation is difficult, additional inferior capsule may be released.

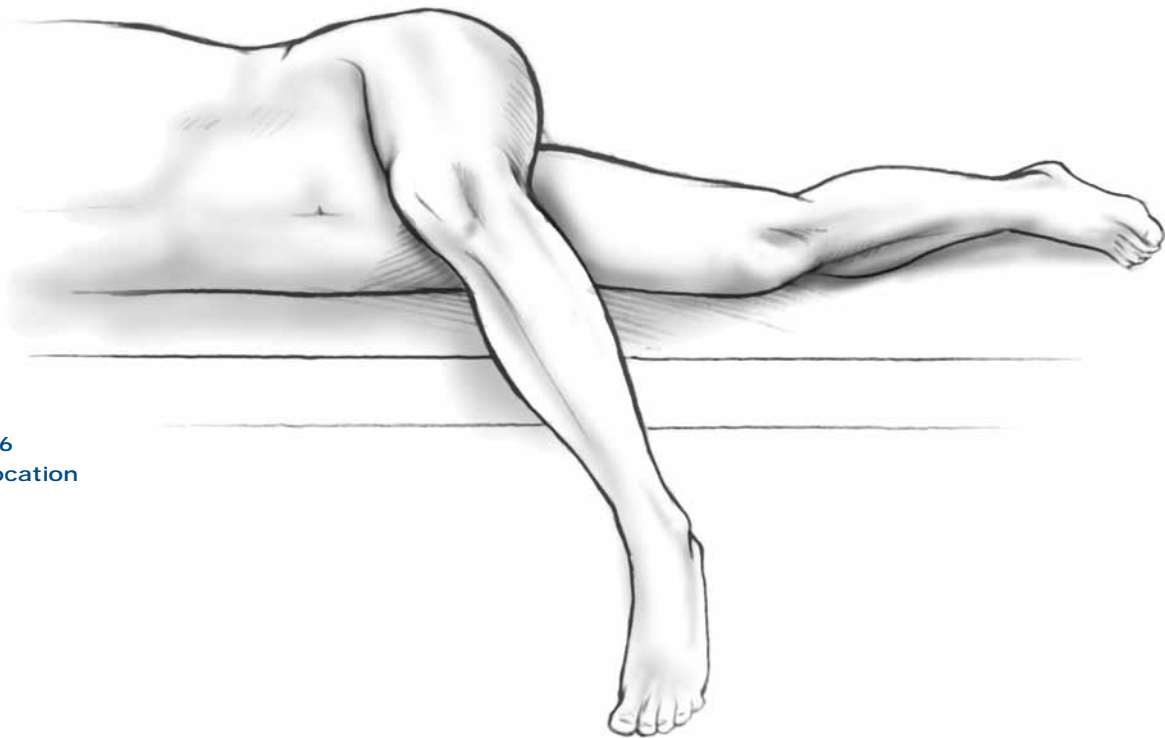


FIGURE 6
Hip Dislocation

Perform a femoral neck osteotomy based upon the protocol for the selected femoral prosthesis. Exposure of the acetabulum is accomplished by placing the leg back on the table in slight flexion and external rotation. Use a self-retaining retractor to spread the medius and minimus anteriorly and the hip capsule posteriorly (FIGURE 7). Carefully place another retractor over the anterior inferior wall of the acetabulum. The final retractor is placed in the acetabular notch beneath the transverse ligament and pulls the femur posteriorly (FIGURE 8).

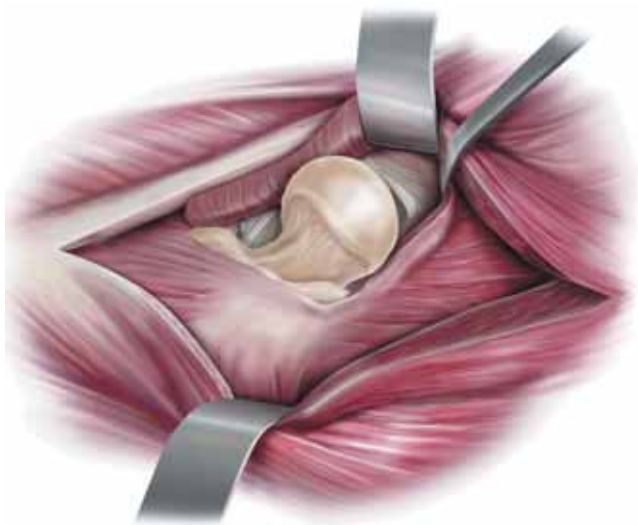


FIGURE 7
Femoral Neck Osteotomy

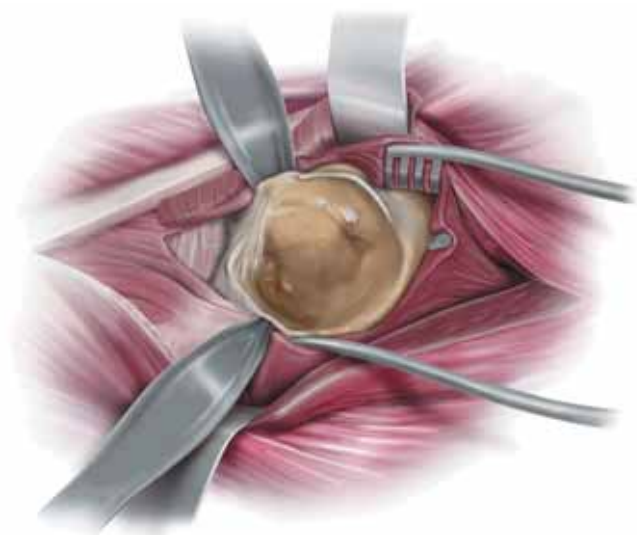


FIGURE 8
Acetabular Exposure

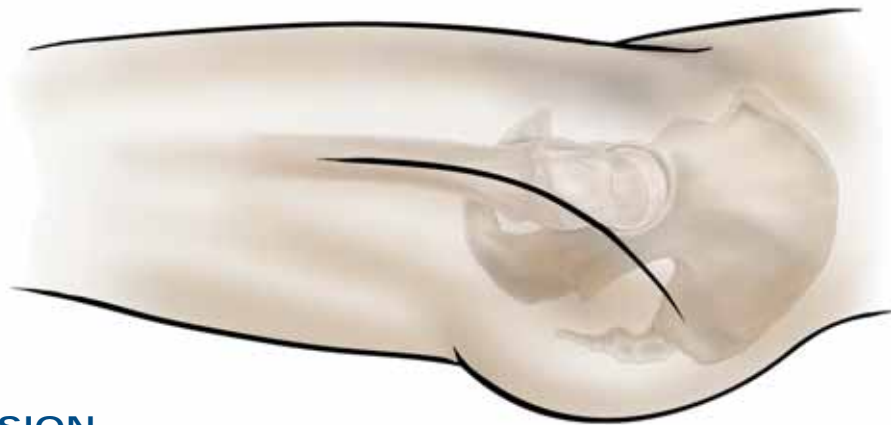
POSTEROLATERAL SURGICAL APPROACH

Use the approach with which you are most familiar and achieve the best surgical result. The Pinnacle Acetabular Cup System instrumentation was designed to accommodate all surgical approaches.

For the posterolateral approach, place the patient in the lateral decubitus position. Ensure that the operating table is parallel to the floor and that the patient is adequately secured to the table to improve accuracy of the external alignment guides.

Center the skin incision over the greater trochanter, carrying it distally over the femoral shaft for about 15 cm and proximally in a gently curving posterior arc of about 30 degrees for about the same distance (FIGURE 9).

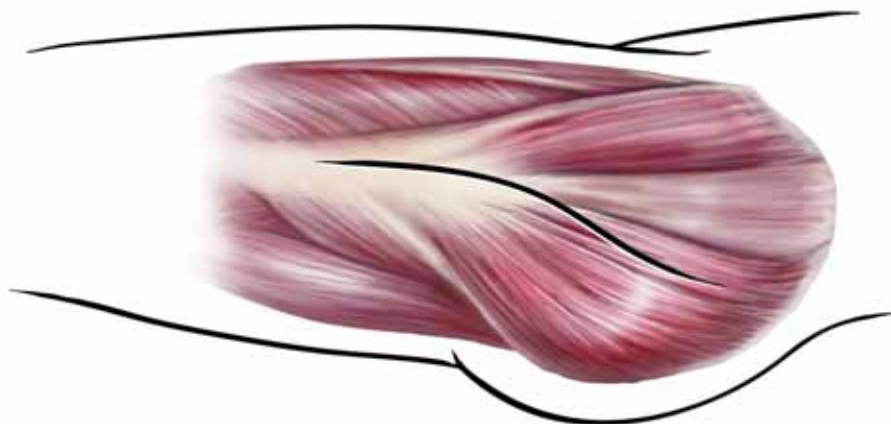
FIGURE 9
Skin Incision



FASCIAL INCISION

Incise the iliotibial tract distally following the skin incision. Develop the incision proximally by blunt dissection of the gluteus maximus along the direction of its fibers (FIGURE 10).

FIGURE 10
Fascial Incision



INITIAL EXPOSURE

Place the leg in extension and internal rotation. Utilize self-retaining retractors to facilitate the exposure. Gently sweep loose tissue posteriorly, exposing the underlying short external rotators and quadratus femoris. Identify the posterior margin of the gluteus medius muscle proximally and the tendon of the gluteus maximus distally (FIGURE 11). Use caution to protect the sciatic nerve.

Incise the quadratus femoris, leaving a cuff of tissue for later repair (FIGURE 12). This exposes the terminal branch of the medial circumflex artery, which lies deep to the proximal third of the quadratus femoris. Identify the piriformis tendon, the obturator internus tendon (conjoint with the gemelli tendons) and the tendon of the obturator externus, and free them from their insertions at the greater trochanter. The piriformis and the conjoint tendon may be tagged for subsequent reapproximation.

FIGURE 11
Short External Rotators

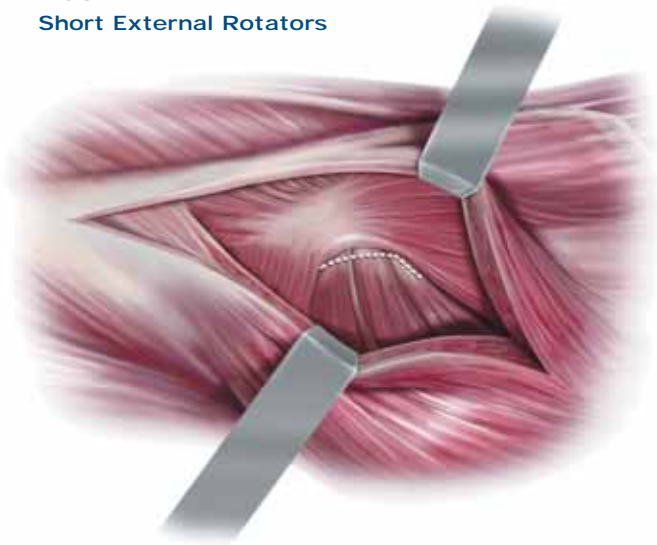
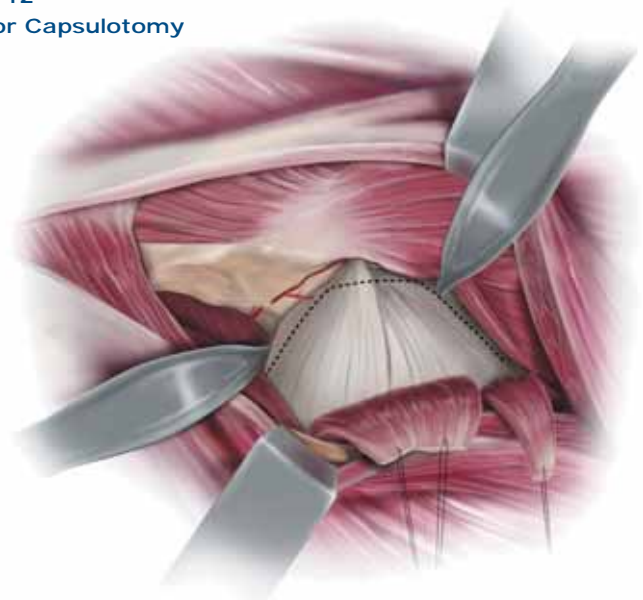


FIGURE 12
Posterior Capsulotomy



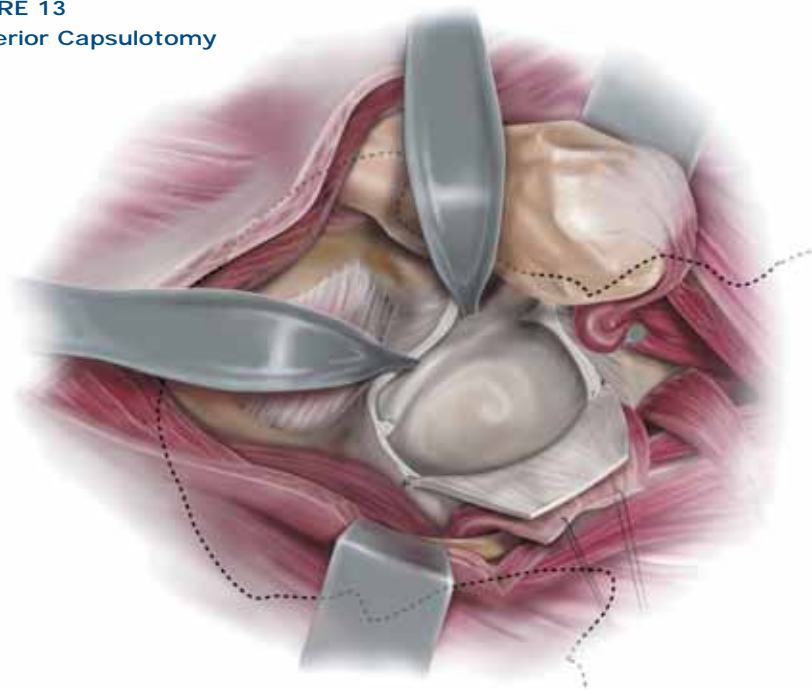
POSTEROLATERAL SURGICAL APPROACH

POSTERIOR CAPSULOTOMY

Retract the short rotator muscles posteromedially together with the gluteus maximus (with consideration to the proximity of the sciatic nerve), thus exposing the posterior capsule (refer to figure 12). Place cobra retractors anteriorly and inferiorly (**FIGURE 13**).

Open the capsule posteriorly starting at the acetabular margin at about 12 o'clock and heading to the base of the neck, around the base of the neck inferiorly and back to the inferior acetabulum, creating a posteriorly based flap for subsequent repair. Excise additional anterosuperior capsule to enhance dislocation of the hip. Alternatively the capsule can be excised.

FIGURE 13
Posterior Capsulotomy



FEMORAL RESECTION

Place a superior pin or retractor in the ilium at approximately the 12 o'clock position. The pin placement is approximately 2 cm superior to the acetabular margin. Caution should be taken not to penetrate the medial wall of the ilium. Measure leg length and dislocate the hip through a combination of flexion, adduction and internal rotation.

Osteotomize the femoral neck in accordance with the protocol of the femoral component you have selected.

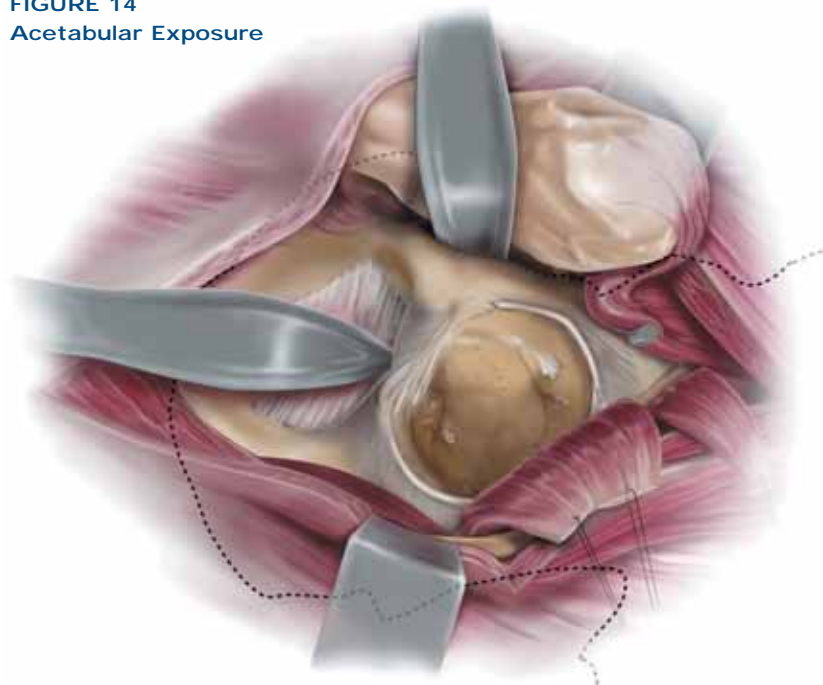
ACETABULAR EXPOSURE

One key to proper acetabular component positioning is adequate surgical exposure. Following femoral neck resection, pass a curved retractor, which straddles the pubis, or a blunt cobra over the anterior column to displace the femur anteriorly (FIGURE 14).

Position a second retractor at the acetabular notch, inferior to the transverse acetabular ligament. An additional retractor may be positioned posteriorly to retract the capsule or short external rotators.

Care should be taken to position retractors to avoid injury to the sciatic nerve. Obtain an unobstructed view of the acetabulum. Excise the entire labrum and remove osteophytes to identify the true anterior and posterior acetabular margins. Release or resect the transverse ligament, together with any accompanying osteophytes. A branch of the obturator artery is often encountered. Clear all soft tissue from the fovea to define the true medial wall.

FIGURE 14
Acetabular Exposure



ACETABULAR REAMING

The goal of acetabular reaming is to restore the center of the original acetabulum. Initially employ a grater 6-8 mm smaller than the anticipated acetabular component size to deepen the acetabulum to the level determined by preoperative templating (FIGURES 15 and 16).

Subsequent reaming should proceed in 1-2 mm increments. Center the reamers in the acetabulum until the deepened socket becomes a true hemisphere. Use a curette to free all cysts of fibrous tissue. Pack any defects densely with cancellous bone.

FIGURE 15
Acetabular Reaming



FIGURE 16
Acetabular Reaming



It is important to understand that all Pinnacle system instrumentation is marked with true dimensions. The graters, shell trials and actual Pinnacle shells are all 180 degrees (FIGURE 17).

Under-reaming of the acetabulum is dependent on bone quality and the size of the acetabular component. A 1 mm under-ream is usually sufficient in smaller sockets, while a larger socket may require 1-2 mm under-ream. Likewise, soft bone will more readily accommodate a greater press-fit of the acetabular component than sclerotic bone.

FIGURE 17



ACETABULAR SHELL TRIALING AND POSITIONING

DETERMINING THE ABDUCTION ANGLE

The preoperative A/P X-ray can help determine the ideal abduction angle (FIGURE 18). The lateral ilium is a useful landmark as an intraoperative guide to a proper abduction angle. In a normal acetabulum with good lateral coverage, if the implanted socket lies flush with a normal lateral pillar, the abduction angle is usually correct (FIGURE 19).

However, degenerative sockets often have deficient lateral covering. The preoperative A/P X-ray can be helpful in determining how much of the acetabular component should be left uncovered to provide the proper implant abduction angle (FIGURE 20).

FIGURE 18

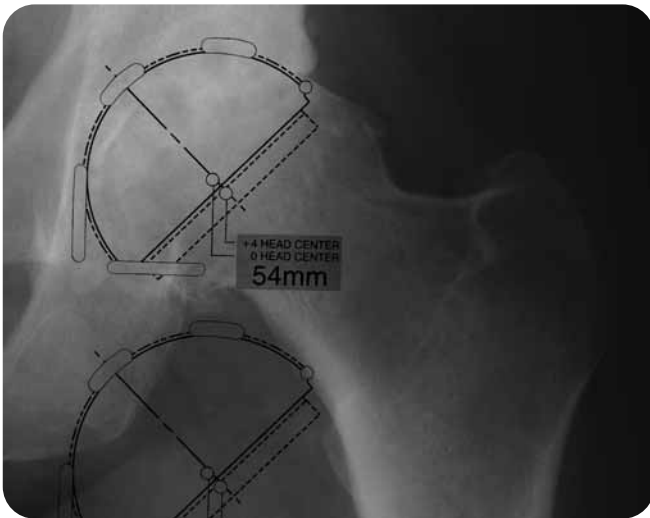


FIGURE 20

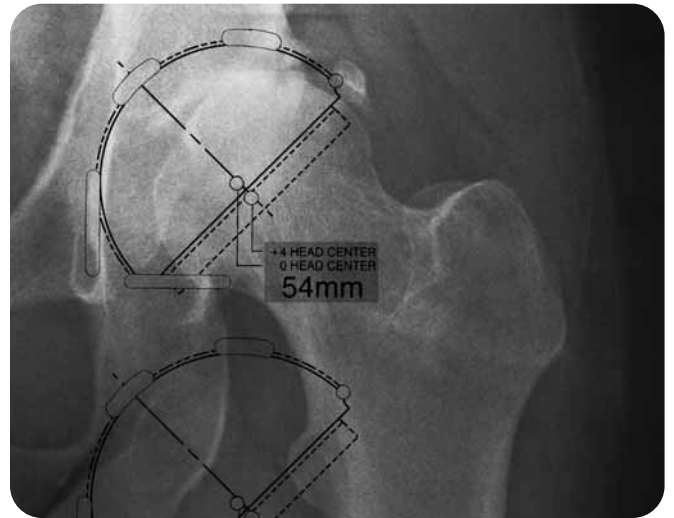


FIGURE 19
Shell Abduction



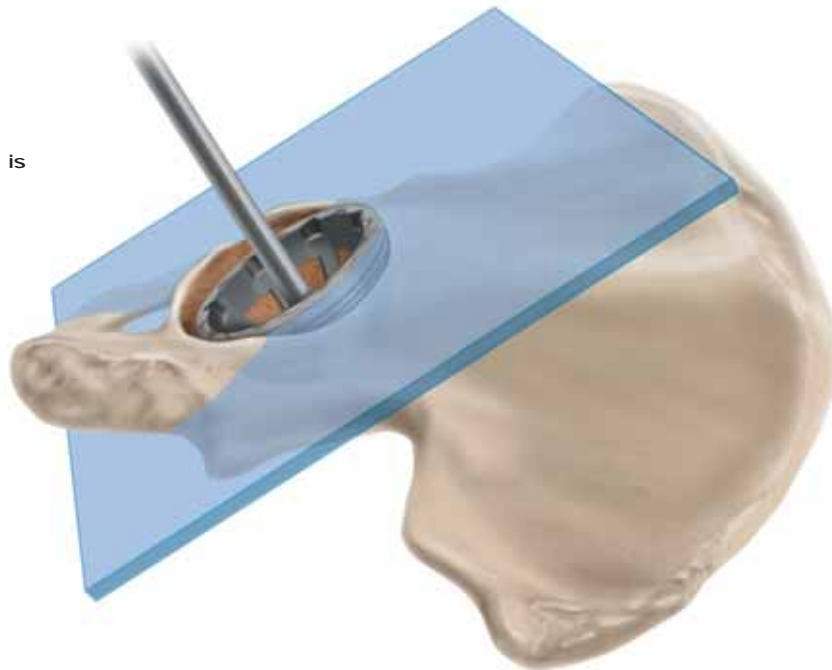
DETERMINING PROPER ANTEVERSION

The most reliable method for determining proper anteversion is the use of the bony landmark. Other methods are subject to error through a change in patient position during the procedure. Defining the bony landmarks of the ischium and pubis during exposure greatly facilitates proper acetabular component position. The plane created by the pubis and the ischium can serve as a guide for proper acetabular shell orientation. The cup should be slightly more anteverted than the pubis/ischial plane. This relationship should remain constant regardless of the depth of reaming (FIGURE 21).

Shell trials in 1 mm incremental sizes are available to assess shell fit and orientation. Contingent on the quality of the prepared bone, select the acetabular trial equal to or 1 mm larger in diameter than the final grater size. The size of the shell trial is as marked on the trial shell (54 mm measures 54 mm). Peripheral rim ridges on the shell trial enhance the stability of the trial shell through trial reduction. Even liner trials fit both odd and even shell trials. For example, a 54 mm polyethylene liner trial fits both the 54 mm and the 53 mm shell trials. Using shell and liner trials in conjunction with the femoral component trials aids in ensuring optimum position of the components.

Place the shell trial in an anatomic orientation with an abduction 35-50 degrees to the transverse plane (refer to figure 19) and 15-30 degrees anteversion.

FIGURE 21
Shell anteversion is typically 15°-20°.



ACETABULAR SHELL TRIALING AND POSITIONING

Confirm complete shell trial seating by sighting through the holes and cutouts in the acetabular shell trial. The screw hole pattern in the trial shell replicates the Sector™ shell implant screw hole pattern to assist with screw targeting. Do not use the shell trial to prepare screw holes. Prepare screw holes only through the final implant. Appropriate trial shell orientation can be verified with external alignment guides in addition to bony landmarks.

FIGURE 23

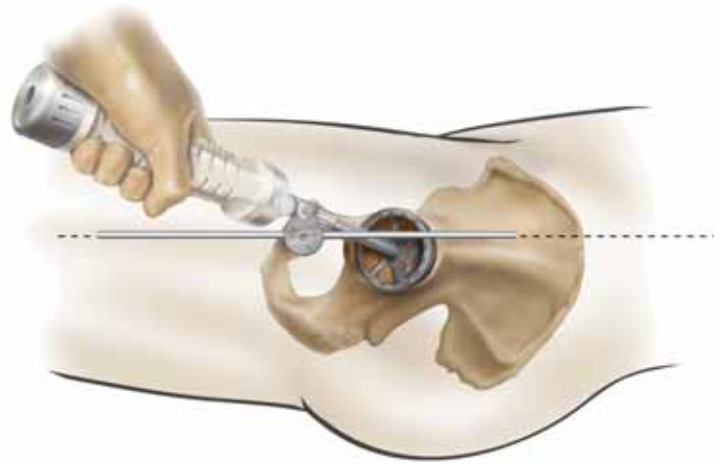
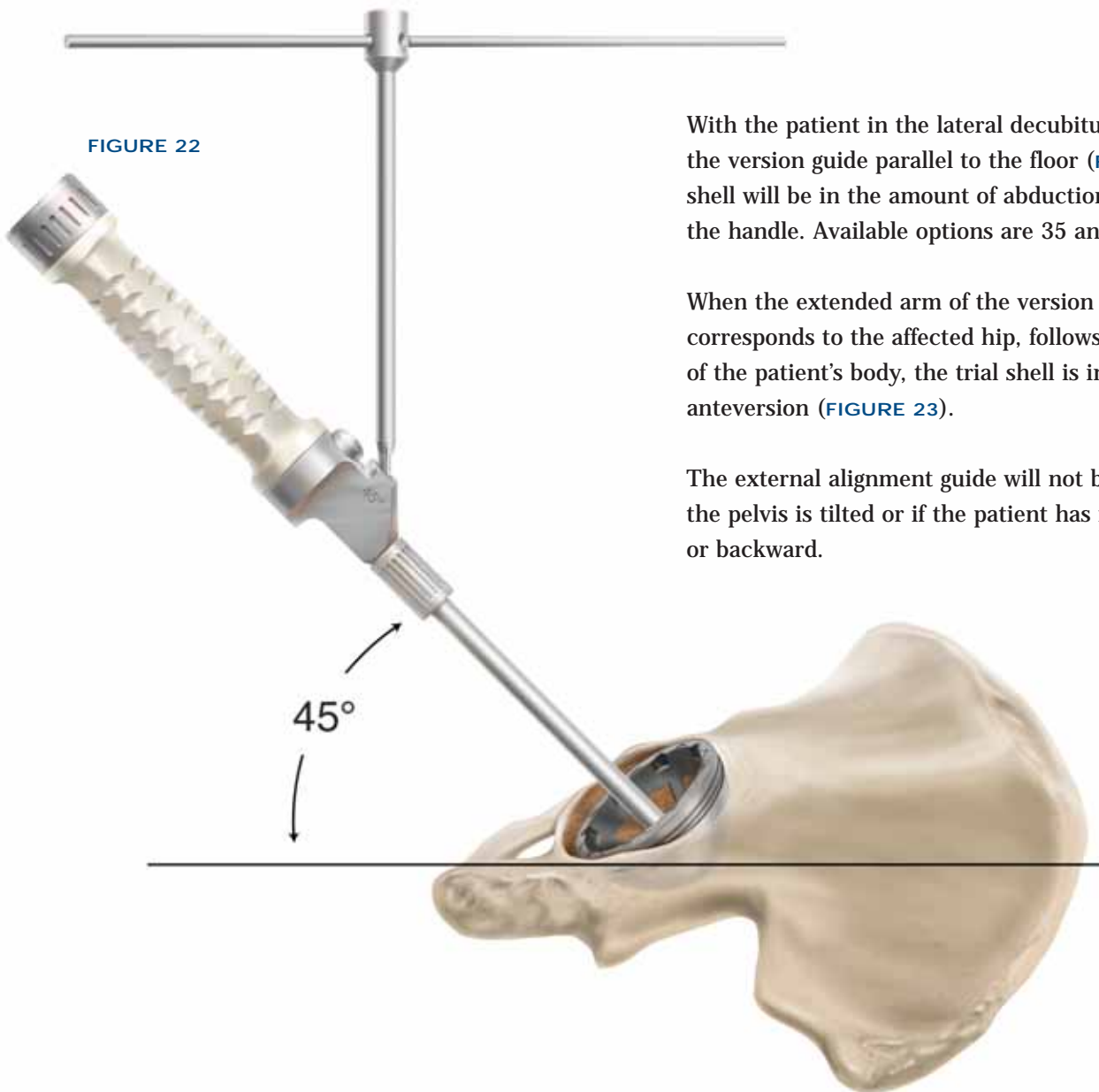


FIGURE 22



With the patient in the lateral decubitus position and the version guide parallel to the floor (FIGURE 22) the shell will be in the amount of abduction selected on the handle. Available options are 35 and 45 degrees.

When the extended arm of the version guide, which corresponds to the affected hip, follows the long axis of the patient's body, the trial shell is in 30 degrees of anteversion (FIGURE 23).

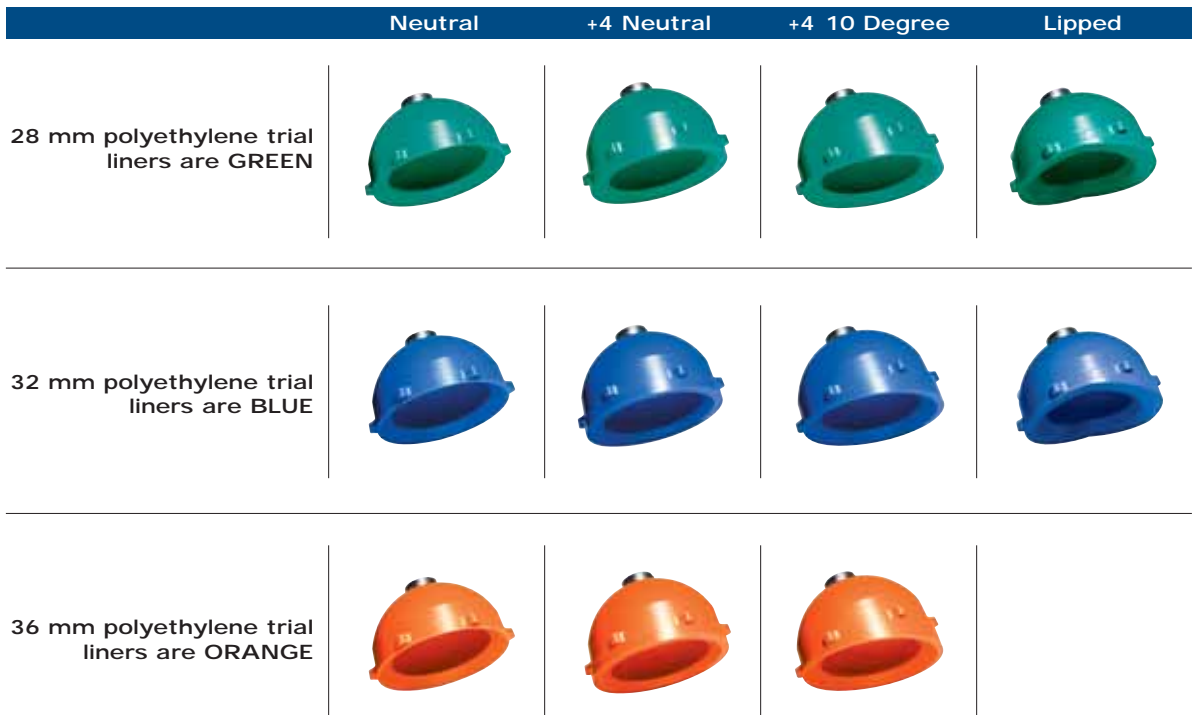
The external alignment guide will not be accurate if the pelvis is tilted or if the patient has rolled forward or backward.

ACETABULAR TRIAL LINERS

Following positioning and seating of the acetabular shell trial, place a liner trial into the trial shell. Secure the liner trial to the shell trial through the apical hole screw using a standard hex head screwdriver. There are four alternative liner configurations for 28 and 32 mm inner diameter (ID) polyethylene liners and three configurations for 36 mm inner diameter polyethylene liners (FIGURE 24). With the femoral component trials in position, assess stability and range of motion. Couple the liner trial with the shell trial in the desired position. For liner alternatives other than neutral, there is an orientation reference etch mark on the liner trial and liner implant.

Shell and Liner Trial Sizes	
Shell Trial Size (mm)	Liner Trial Size (mm)
47, 48	48
49, 50	50
51, 52	52
53, 54	54
55, 56	56
57, 58	58
59, 60	60
61, 62	62
63, 64	64
65, 66	66

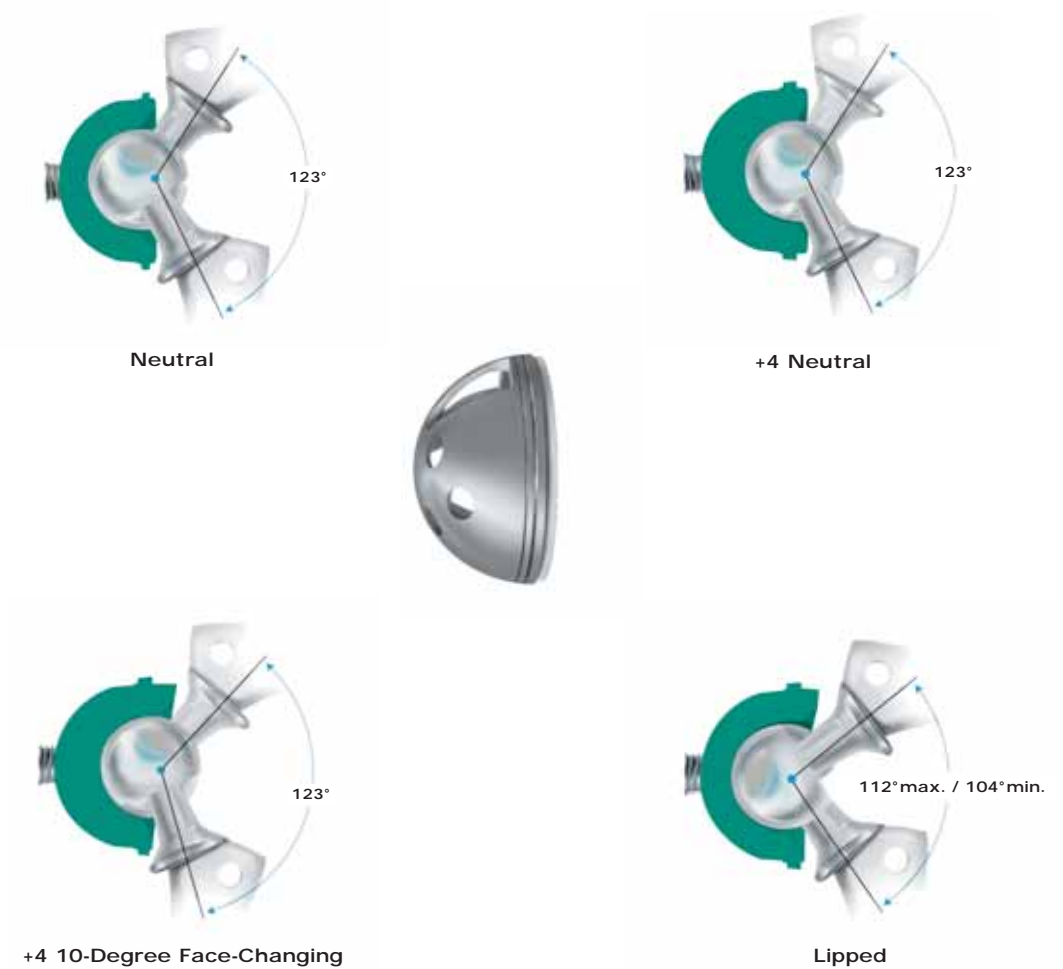
FIGURE 24



LINER CONFIGURATIONS

In the Pinnacle system, a variety of liner designs are available. Each design has specific benefits. It is important for the surgeon to understand the geometry of the various liner alternatives and their impact on joint biomechanics and range of motion (FIGURE 25).

FIGURE 25
Liner Alternatives – 28 mm ID with AML stem



Neutral Liner

The neutral liner provides 180 degrees of head coverage. The wide face chamfer is optimized for range of motion. The range of motion measured is 123 degrees with a standard 12/14 taper stem and a 28 mm head. The femoral head's center of rotation is concentric with the outer diameter of the shell.

+4 Neutral Liner

Like the neutral liner, the +4 mm neutral liner provides 180 degrees of head coverage. The wide face chamfer is optimized for range of motion. The range of motion measured is 123 degrees with a standard 12/14 taper stem and a 28 mm head. This liner provides a 4 mm lateralization of the femoral head's center of rotation. This 4 mm offset both increases soft tissue tensioning and provides 4 mm of increased polyethylene thickness in the shell's dome region. This lateralized liner can be used as an alternative to a longer neck and may enable the surgeon to avoid using a skirted head. A +4 mm lateralized liner will result in about 3 mm of leg length and about 3 mm of offset if the cup is inserted at a 45-degree abduction angle.

+4 10-Degree Face-Changing Liner

Like the other liners, the +4 10-degree liner provides 180 degrees of head coverage and the wide chamfer is optimized for range of motion, 123 degrees with a 12/14 taper and a 28 mm head. This liner lateralizes the femoral head 4 mm and a 10-degree face change alters inclination/version dependent upon placement of the liner.

Lipped Liner

This liner provides 180 degrees of head coverage, plus a 4 mm vertical wall to enhance stability. The range of motion is measured at 112 degrees max. / 104 degrees min. with a standard 12/14 taper. The lip on this liner can provide additional stability; however, the impact on range of motion and early impingement must be understood.

Polyethylene Liner Chart

	Neutral	+4 Neutral	+4 10-Degree Face-Changing	Lipped
28 mm	123°	123°	123°	112°/104°
32 mm	129°	129°	129°	124°/113°
36 mm	130°	130°	130°	N/A

ROM tested with 12/14 taper AML stem.

IMPLANTING THE ACETABULAR SHELL

SHELL INSERTION

Each Pinnacle shell style is implanted using the same basic surgical technique; however, some shell styles have technique-specific tips that help facilitate implantation. This technique demonstrates the insertion of a 100 series (no-hole) shell. The following sections also examine techniques for Sector (three-hole) and 300 (tri-spike) series shells. Before implanting the final prosthesis, take the hip through a full range of motion and stability assessment with all trial components in position.

Securely thread the permanent acetabular shell prosthesis onto the acetabular cup positioner (FIGURE 26). Use the acetabular alignment rod, with optional positions of 35 and 45 degrees of abduction, to assist in component orientation (refer to figure 23).

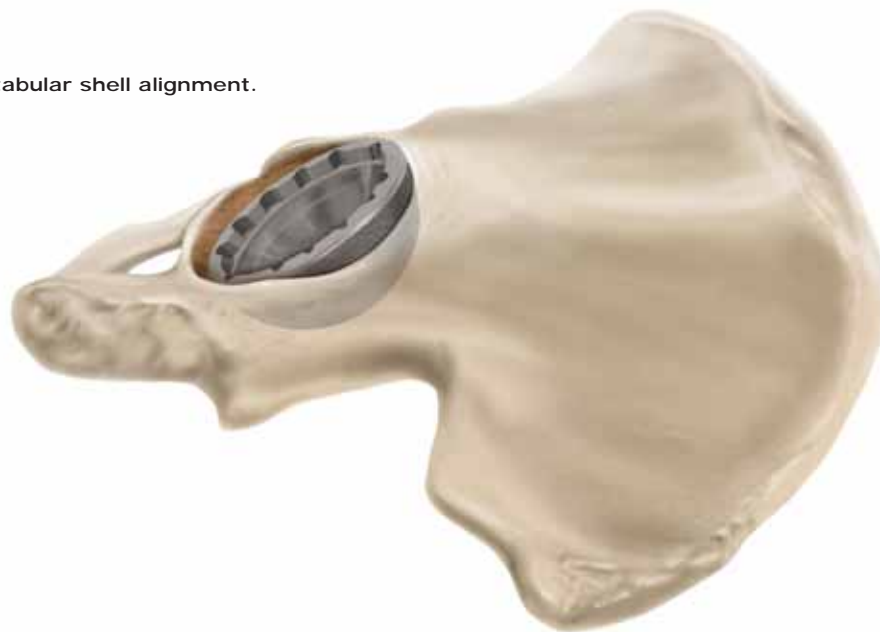
Anteversion is typically set at 15-30 degrees. Establish this orientation through visual confirmation that the acetabular component is directed fully into the acetabulum. The external alignment guide should be used in conjunction with appropriate bony landmarks and the position of the acetabular trial to determine the best position for the acetabular component (refer to figure 22).

FIGURE 26



After confirming alignment, impact the prosthesis into position (FIGURE 27). Given the nature of a hemispherical acetabular component, rim contact will occur before dome seating occurs. This may require additional impaction to ensure seating. Confirm seating by sighting through the apical hole or, if present, screw holes. An apical hole eliminator may be inserted with a standard hex head screwdriver following shell impaction. Following final component seating, if adjustments to the shell orientation are necessary, thread the impactor handle back into the apical hole to adjust the cup position. Avoid using a punch in the taper region to adjust shell position.

FIGURE 27
Confirm acetabular shell alignment.



IMPLANTING THE ACETABULAR SHELL WITH SCREW FIXATION

SCREW INSERTION

The Sector shell has three screw holes and is designed for insertion with screws. Quickset Acetabular Screw Instruments are recommended for screw insertion. Two medial hole alternatives are placed to enable screw placement up the posterior column in either the right or left hip. The single lateral screw provides additional access to the ilium.

Select holes where the prosthesis is to be anchored with cancellous screws so that the screws lie within a safe quadrant. The safe quadrant is defined by two lines from the anterior-inferior iliac spine through the center of the acetabulum and posterior by a line from the sciatic notch to the center of the acetabulum (FIGURE 28).

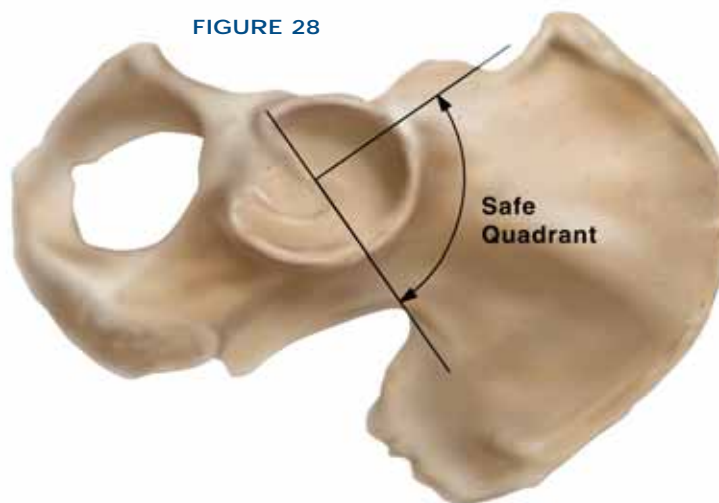


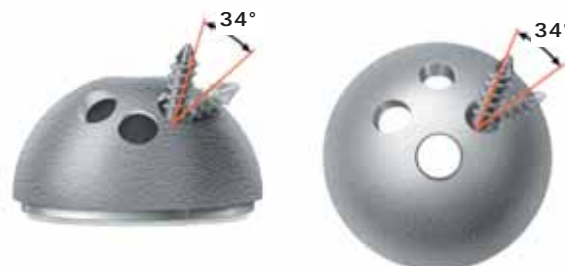
FIGURE 28

The drill bit is controlled by the drill guide as it passes through selected holes into the acetabulum (FIGURE 29). The screw angle may vary by as much as 34 degrees (FIGURE 30). The effective lengths of the four drill bits available are for 25, 35, 45 and 70 mm. By seating the drill bit completely into the guide, holes corresponding to the effective length of the drill bit will be created.

FIGURE 29
Drill Guide



FIGURE 30
Screw Angulation



Verify hole depth using the Quickset depth gauge. Alternating colors on the depth gauge represent 10 mm increments (FIGURE 31).

FIGURE 31
Depth Gauge

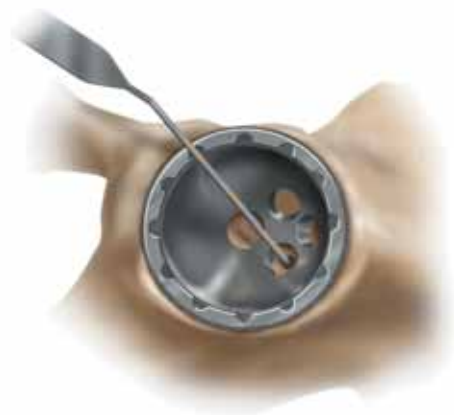


FIGURE 32
Screw Insertion



Insert 6.5 mm Pinnacle cancellous bone screws using a hex head screwdriver (FIGURES 32 and 33). The 6.5 mm self-tapping screws have four-point cutting flutes with a blunt tip to reduce the risk of neurovascular injury (FIGURE 34).

FIGURE 33



FIGURE 34



IMPLANTING THE ACETABULAR SHELL WITH SPIKES

300 SERIES SHELL INSERTION

Spike placement along the radius of the shell is the same as the clinically established Duraloc 300 series shell (FIGURES 35 and 36). The spikes are coated for additional fixation but have been reduced in length by 1.5 mm in height compared to the Duraloc shell. This reduction in spike height does not alter fixation but ensures that the spike contacts bone on insertion at the same point that the shell contacts the rim of

the prepared acetabulum. This gives the surgeon greater control when inserting the 300 series shell and ensures the shell bottoms out in the dome of the acetabulum. **The recommended acetabular reaming technique for the Pinnacle 300 shell is either 1 mm under or line-to-line dependent on bone quality.** It is important that the cup is well centered in the prepared acetabular cavity in the predetermined alignment indicated by the trial before being impacted.

FIGURE 35
Prior to shell impaction, spikes and rim engage simultaneously when the shell is centered and aligned.



FIGURE 36



Spike Orientation



Spike Length

POLYETHYLENE LINER INSERTION AND IMPACTION

Following insertion of the final acetabular shell and femoral component, the trial liners can be used in the shell to confirm liner selection and evaluate joint stability and range of motion.

Prior to inserting the final acetabular liner, thoroughly irrigate and clean the shell. It is important to check the shell/liner locking groove for debris. Remove all soft tissue from the face of the shell so as not to impede liner seating (FIGURE 37). An apex hole plug may be used prior to liner insertion.

FIGURE 37
Liner Insertion



POLYETHYLENE LINER INSERTION AND IMPACTION

Prior to insertion/impaction, mate the liner anti-rotational device (ARD) tabs with the ARD scallops on the shell (FIGURE 38). There are six ARD tabs on the liners and 12 ARD scallops in the shell. This allows the liner to be rotated in 30-degree increments. Seat the liner using the ID liner impactor that corresponds to the selected implant. Because the locking mechanism is tapered, it is important to impact the liner directly into the shell with multiple medium blows (FIGURE 39).

Impacting the liner in a tilted position may prevent complete seating. Seating is visually confirmed when the liner ARDs are flush with the face of the acetabular shell; however, the liner face will remain proud in relation to the shell face by approximately 1 mm (FIGURE 40).

FIGURE 38
Align the liner anti-rotation tabs with shell scallops.



FIGURE 39
Liner Impaction

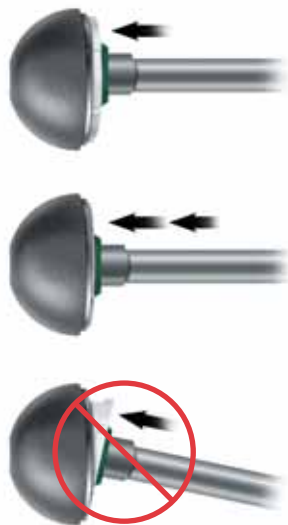


FIGURE 40
Liner Seating Height

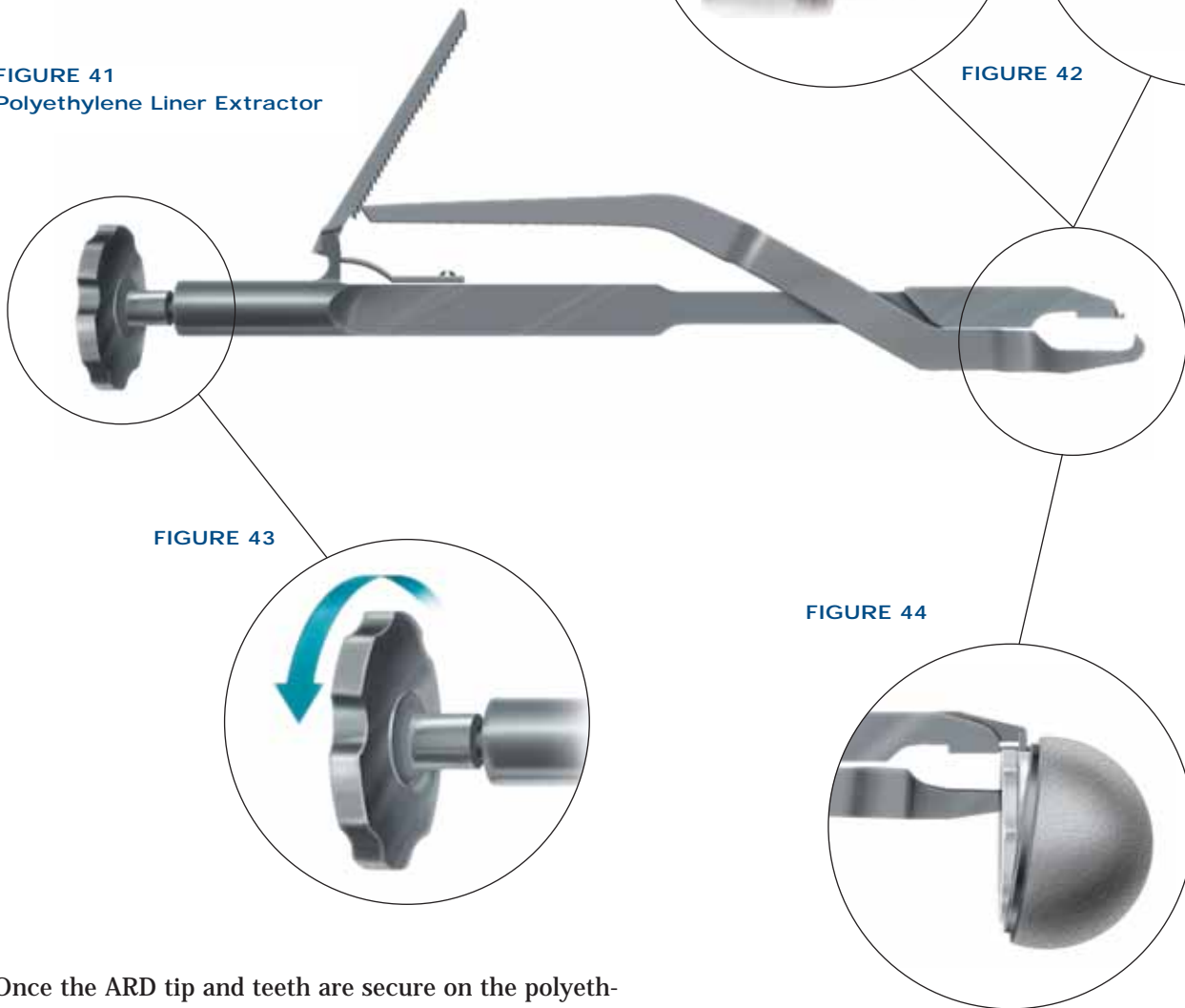


POLYETHYLENE LINER EXTRACTION

A polyethylene liner extractor is available to aid in polyethylene liner extraction and to help ensure the Pinnacle shell is not damaged during polyethylene liner extraction (FIGURE 41).

Open the extractor jaws and extend the ARD pin from the extractor tip. Place the ARD pin into an empty ARD and tightly close the jaws of the extractor (FIGURE 42). The teeth of the extractor should dig into the inner diameter of the polyethylene.

FIGURE 41
Polyethylene Liner Extractor



Once the ARD tip and teeth are secure on the polyethylene, advance the extraction knob clockwise until the polyethylene is removed (FIGURES 43 and 44). It is important to note that an extracted polyethylene liner cannot be reused.

ULTAMET METAL LINER INSERTION

To ensure optimal component placement when using alternative bearings, trialing is critical. Dedicated trials for alternative bearings exist that help ensure the correct restoration of biomechanics. The 28 mm alternative bearing trials are yellow and the 36 mm alternative bearing trials are purple.

If correct joint biomechanics, free of mechanical impingement, cannot be obtained with the alternative bearing trials, perform a trial reduction using the Pinnacle polyethylene liner trials. Then, use the Pinnacle polyethylene liner that results in joint stability.



28 mm alternative bearing trial



36 mm alternative bearing trial

Before placing the Ultamet insert into the Pinnacle shell, ensure all mating surfaces are clean and free of debris (FIGURE 45). Handle the Ultamet metal insert carefully to avoid damage that could compromise the mechanical integrity of the insert taper locking mechanism.

Use only the following femoral heads with the Ultamet metal-on-metal insert. Use of femoral heads other than those indicated here is contraindicated and will compromise performance.

Articul/eze® M Head, 28 mm	(12/14 Taper)
Cat. No.	Size (mm)
1365-11-500	+1.5
1365-12-500	+5
1365-13-500	+8.5

Articul/eze M Head, 36 mm	(12/14 Taper)
Cat. No.	Size (mm)
1365-50-000	-2
1365-51-000	+1.5
1365-52-000	+5
1365-53-000	+8.5
1365-54-000	+12
1365-55-000	+15.5

FIGURE 45
Ensure all taper mating surfaces are clean and free of debris.



Attach the suction cup inserter to the metal insert ID in any angle that facilitates introduction of the insert into the acetabular shell. Cautiously advance the metal insert to ensure circumferential alignment of the taper mechanism (FIGURE 46). Palpate the metal insert to confirm proper taper alignment and seating in the shell. The liner should fit flush relative to the face of the shell. Apply finger pressure to ensure initial locking of the taper mechanism. Do not attempt to fully engage the taper locking mechanism by striking the end of the suction cup inserter.

The Ultamet Metal-on-Metal Articulation was designed in consultation with Drs. C. Anderson Engh, Brian Haas, Thomas Schmalzried and Ray Wasielewski.

S-ROM® M Head, 28 mm	(11/13 S-ROM Taper)
Cat. No.	Size (mm)
1365-16-500	+0
1365-17-500	+3
1365-18-500	+6

S-ROM M Head, 36 mm	(11/13 S-ROM Taper)
Cat. No.	Size (mm)
1365-26-000	-3
1365-31-000	+0
1365-32-000	+3
1365-33-000	+6
1365-34-000	+9
1365-36-000	+12

SUCTION CUP INSERTION TECHNIQUE



FIGURE 46
Confirm proper taper alignment of metal insert.

FIGURE 47
Release suction cup inserter.



It is important to cautiously release the suction cup insertion instrument from the Ultamet insert so the insert does not disengage from the shell. It is recommended that the Ultamet insert be secured with a thumb and forefinger placed superiorly and inferiorly while the suction cup instrument is disengaged from the insert (FIGURE 47).

Prior to final impaction, examine the insert to ensure it is seated evenly relative to the shell face. Use an impactor with the appropriate head size for final seating of the metal insert. Final seating requires two to four sharp blows (FIGURE 48).

FIGURE 48
Verify insert alignment and impact insert.



GRIPPER INSERTION TECHNIQUE

STEP 1

Assemble the appropriate size gripper to the inserter shaft aligning the slot of the gripper with the pin of the shaft (FIGURE A).



STEP 2

Thread the appropriate size tip to the shaft (FIGURE B). After threading on the tip, pull the gripper down until it contacts the tip (FIGURE C).

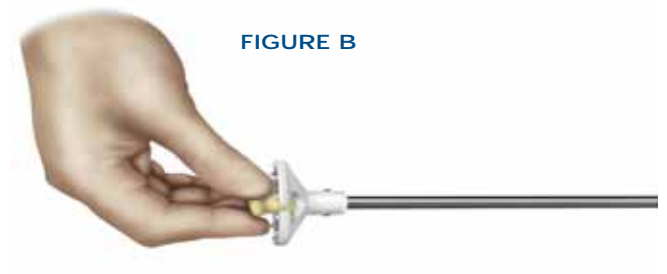


FIGURE C



STEP 3

Press-fit the insert on the gripper component (FIGURE D). Verify that the insert is fully seated to ensure proper alignment (FIGURE E).



FIGURE D



FIGURE E

STEP 4

Cautiously advance the insert into the incision and align the face of the gripper to the face of the cup (FIGURE F and FIGURE G).



FIGURE F



FIGURE G

STEP 5

Proper alignment is achieved when the instrument will no longer rotate due to the locking features between the gripper cup (FIGURE H).



FIGURE H

STEP 6

Press firmly on handle to introduce the insert into the cup (FIGURE I).

Do not attempt to fully engage the taper locking mechanism by striking the end of the Gripper Inserter.



FIGURE I

STEP 7

Carefully remove instrument (FIGURE J).



FIGURE J

STEP 8

Palpate the insert to confirm proper taper alignment and seating in the shell (FIGURE K).

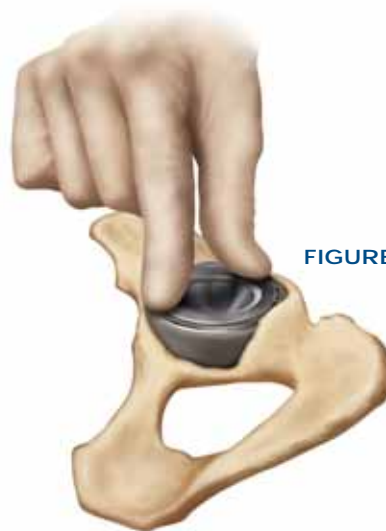
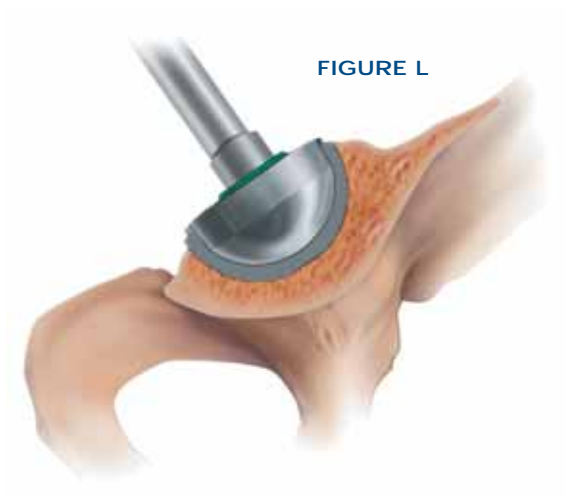


FIGURE K

STEP 9

Use an impactor with the appropriate head size for final seating of the metal insert (FIGURE L). Final seating requires two to four sharp blows (FIGURE M).



STEP 1

If it is necessary to remove an Ultamet insert from a Pinnacle shell, thread the extractor handle onto the appropriate size alternative bearing (AB) extractor (each shell size has a specific extractor, e.g., 48 mm shell uses a 48 mm extractor) (FIGURE 49).

Note: Can be used with 28 or 36 mm ID inserts.

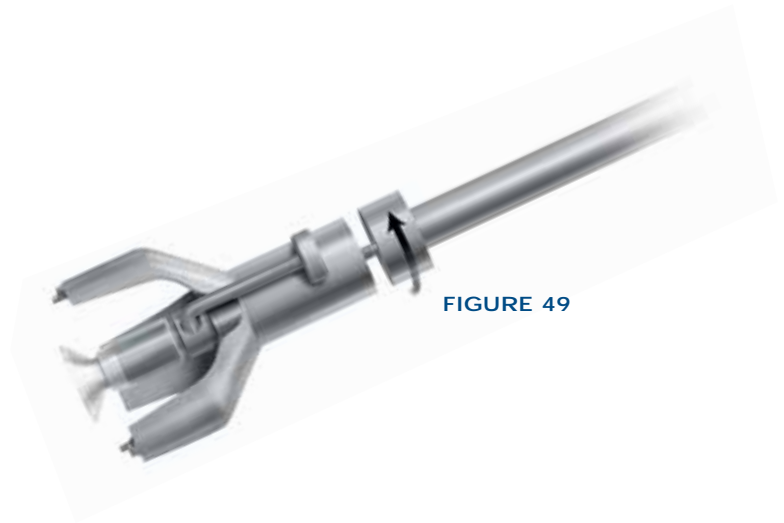


FIGURE 49

STEP 2

Place the three tips of the AB extractor into any three scallops on the face of the Pinnacle shell (FIGURE 50).



FIGURE 50

FIGURE 51



STEP 3

Push down the attached lever with thumb pressure to engage the suction cup to the inner diameter of the Ultamet insert (FIGURE 51).

STEP 4

To remove the Ultamet insert from the shell, impact the extraction handle lightly one to two times. The resulting vibration will release the taper lock between the Ultamet insert and the Pinnacle shell. The insert will be lifted out of the shell by the suction cup mechanism (FIGURE 52).

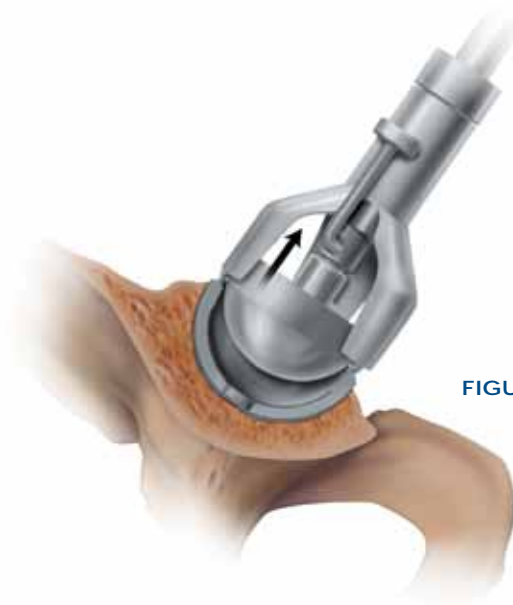


FIGURE 52

FUNCTIONAL ASSESSMENT

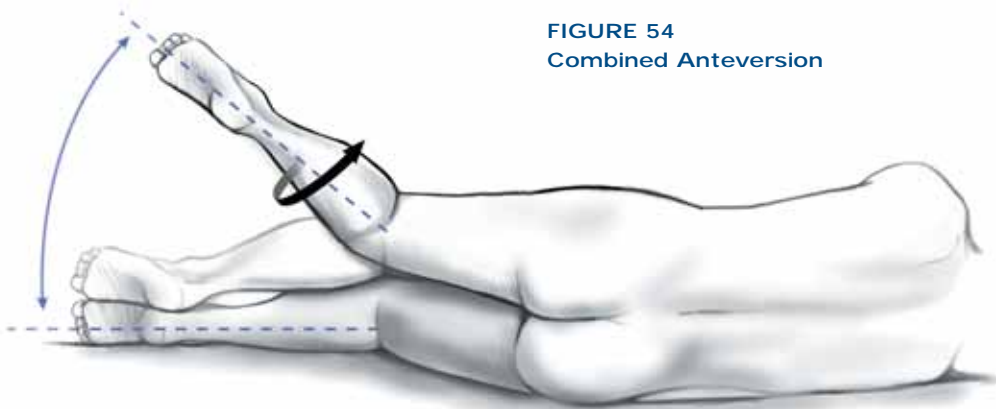
Correct component placement is critical for the longevity of the hip reconstruction. Component placement is even more critical when alternative bearings are used in the reconstruction. The following illustration depicts the position of the femoral component neck with relation to the opening of the acetabular component with the reconstructed hip in neutral rotation (FIGURE 53).

To assess the combined anteversion of the femoral stem and acetabular component, place the patient in the lateral decubitus position with the operative hip gently flexed and internally rotated (FIGURE 54) until the circumference of the femoral head becomes coplanar with the opening of the acetabular liner (i.e., the axis of the femoral neck is perpendicular to the liner face). This position is depicted through a frontal view (FIGURE 55) and through a lateral view (FIGURE 56).

FIGURE 53



FIGURE 54
Combined Anteversion



The angle between horizontal and the internally rotated operative leg provides an estimate of combined anteversion of the acetabular component and the femoral stem. Combined anteversion at 30-40 degrees is generally acceptable.

FIGURE 55

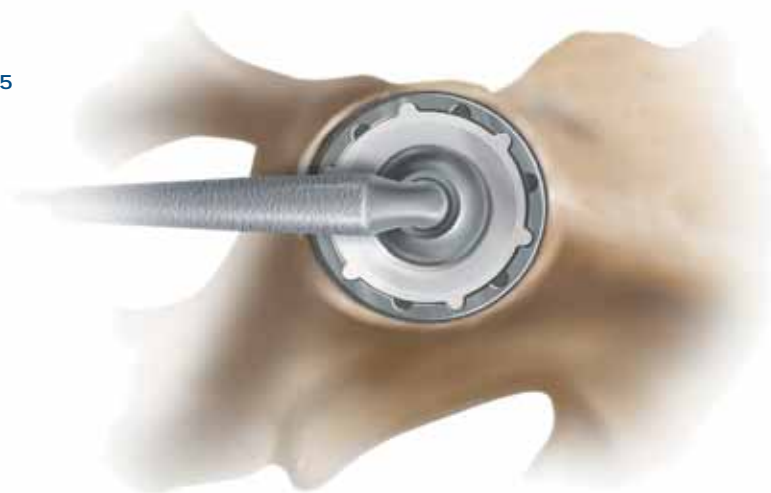
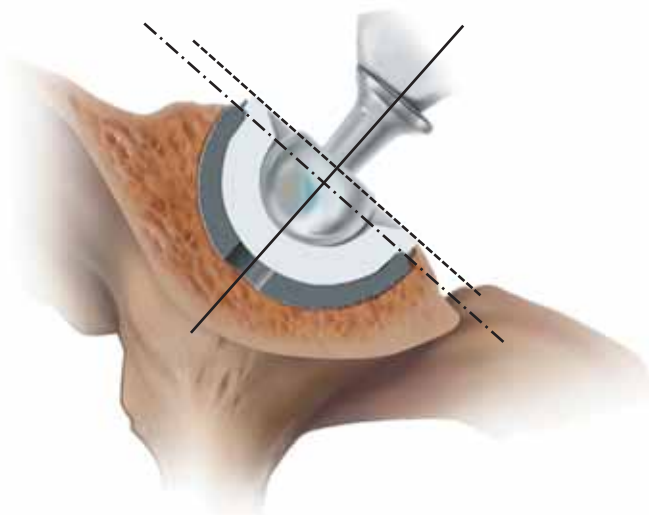


FIGURE 56



TIGHT EXPOSURE AND STABILITY TIPS

TIGHT EXPOSURE

If the exposure is tight, completely incise the anterior capsule, perform a partial or complete release of the gluteus maximus tendon and release the reflected head of the rectus femoris.

STABILITY ASSESSMENT

POSTERIOR INSTABILITY

With the trial implants in place, place the hip in 90 degrees of flexion, neutral abduction and internally rotate until subluxation. If there is less than 60 degrees of internal rotation, determine the cause of instability.

Prosthetic Impingement

Problem ■ Femoral implant neck levers on the component rim.

- Solutions**
- Trial with a face-changing liner and re-evaluate impingement.
 - Reposition shell to correct version/abduction.
 - Increase head size and evaluate.
 - Increase anteversion of the stem.

Bony Impingement

Problems ■ Prosthetic neck levers on anterior acetabular osteophyte.
■ Greater trochanter impinging on ilium.

- Solutions**
- Remove anterior osteophytes from the acetabulum.
 - Increase stem offset to move trochanter away from the ilium.
 - Remove anterior trochanteric bone.
 - Trial with a lateralized liner.

Soft Tissue Impingement

Problem ■ Redundant anterior capsule causes head to lever out of socket.

- Solutions**
- Resect redundant anterior capsule.
 - Trial with a lateralized liner.

Soft Tissue Laxity

Problem ■ Lax soft tissue leading to multidirectional instability.

- Solutions**
- Increase the neck length.
 - Trial with a lateralized acetabular liner.
 - Advance the trochanter.



STABILITY ASSESSMENT

ANTERIOR INSTABILITY

With the implant trial in place, place the hip in extension and maximally externally rotate; subluxation should not occur. If subluxation occurs, assess the following:

Prosthetic Impingement

Problem ■ Prosthetic neck impinges on the acetabular cup.

- Solutions**
- If lipped or face-changing trial liner is in, convert the liner to a neutral liner.
 - Reposition acetabular component to decrease anteversion.
 - Decrease anteversion of the femoral stem.
 - Increase the head size and re-evaluate.

Bony Impingement

Problem ■ Femur impinges on the ischium.

- Solutions**
- Increase femoral offset.
 - Decrease acetabular or stem anteversion.
 - Trial with a lateralized liner.

THE KEYS TO MANAGING STABILITY ARE:

- 1 Ensure the appropriate anteversion/abduction of the acetabular and femoral components.
- 2 Avoid the routine use of lipped liners and skirted heads as these decrease range of motion prior to mechanical impingement.
- 3 Restore correct leg length and femoral offset.
- 4 Repair the posterior capsule and rotators.
- 5 Work with the patient to ensure appropriate postoperative precautions are followed.

CLOSURE

Closure is based on the surgeon's preference and the individual case. If the capsule is retained it is closed separately. The gluteus minimus and gluteus medius can be closed separately or as a single unit. At least one stitch is passed through bone. Tension is relieved during the repair with slight internal rotation. The repair should be tested throughout the hip range of motion.

28 mm STANDARD POLYETHYLENE LINER OPTIONS



Pinnacle Standard Poly Neutral 28 mm ID Liners	
Cat. No.	OD (mm)
1218-28-048	48
1218-28-050	50
1218-28-052	52
1218-28-054	54
1218-28-056	56
1218-28-058	58
1218-28-060	60
1218-28-062	62
1218-28-064	64
1218-28-066	66



Pinnacle Standard Poly +4 Neutral 28 mm ID Liners	
Cat. No.	OD (mm)
1218-28-448	48
1218-28-450	50
1218-28-452	52
1218-28-454	54
1218-28-456	56
1218-28-458	58
1218-28-460	60
1218-28-462	62
1218-28-464	64
1218-28-466	66



Pinnacle Standard Poly +4 10 Degree 28 mm ID Liners	
Cat. No.	OD (mm)
1218-28-148	48
1218-28-150	50
1218-28-152	52
1218-28-154	54
1218-28-156	56
1218-28-158	58
1218-28-160	60
1218-28-162	62
1218-28-164	64
1218-28-166	66



Pinnacle Standard Poly Lipped 28 mm ID Liners	
Cat. No.	OD (mm)
1218-28-248	48
1218-28-250	50
1218-28-252	52
1218-28-254	54
1218-28-256	56
1218-28-258	58
1218-28-260	60
1218-28-262	62
1218-28-264	64
1218-28-266	66

28 mm MARATHON CROSS-LINKED POLYETHYLENE LINER OPTIONS



Pinnacle Marathon Poly Neutral 28 mm ID Liners	
Cat. No.	OD (mm)
1219-28-048	48
1219-28-050	50
1219-28-052	52
1219-28-054	54
1219-28-056	56
1219-28-058	58
1219-28-060	60
1219-28-062	62
1219-28-064	64
1219-28-066	66



Pinnacle Marathon Poly +4 Neutral 28 mm ID Liners	
Cat. No.	OD (mm)
1219-28-448	48
1219-28-450	50
1219-28-452	52
1219-28-454	54
1219-28-456	56
1219-28-458	58
1219-28-460	60
1219-28-462	62
1219-28-464	64
1219-28-466	66



Pinnacle Marathon Poly +4 10 Degree 28 mm ID Liners	
Cat. No.	OD (mm)
1219-28-148	48
1219-28-150	50
1219-28-152	52
1219-28-154	54
1219-28-156	56
1219-28-158	58
1219-28-160	60
1219-28-162	62
1219-28-164	64
1219-28-166	66



Pinnacle Marathon Poly Lipped 28 mm ID Liners	
Cat. No.	OD (mm)
1219-28-248	48
1219-28-250	50
1219-28-252	52
1219-28-254	54
1219-28-256	56
1219-28-258	58
1219-28-260	60
1219-28-262	62
1219-28-264	64
1219-28-266	66

32 mm STANDARD POLYETHYLENE LINER OPTIONS



Pinnacle Standard Poly Neutral 32 mm ID Liners	
Cat. No.	OD (mm)
1218-32-052	52
1218-32-054	54
1218-32-056	56
1218-32-058	58
1218-32-060	60
1218-32-062	62
1218-32-064	64
1218-32-066	66

Pinnacle Standard Poly +4 Neutral 32 mm ID Liners	
Cat. No.	OD (mm)
1218-32-452	52
1218-32-454	54
1218-32-456	56
1218-32-458	58
1218-32-460	60
1218-32-462	62
1218-32-464	64
1218-32-466	66

Pinnacle Standard Poly +4 10 Degree 32 mm ID Liners	
Cat. No.	OD (mm)
1218-32-152	52
1218-32-154	54
1218-32-156	56
1218-32-158	58
1218-32-160	60
1218-32-162	62
1218-32-164	64
1218-32-166	66

Pinnacle Standard Poly Lipped 32 mm ID Liners	
Cat. No.	OD (mm)
1218-32-252	52
1218-32-254	54
1218-32-256	56
1218-32-258	58
1218-32-260	60
1218-32-262	62
1218-32-264	64
1218-32-266	66

32 mm MARATHON CROSS-LINKED POLYETHYLENE LINER OPTIONS



Pinnacle Marathon Poly Neutral 32 mm ID Liners	
Cat. No.	OD (mm)
1219-32-052	52
1219-32-054	54
1219-32-056	56
1219-32-058	58
1219-32-060	60
1219-32-062	62
1219-32-064	64
1219-32-066	66

Pinnacle Marathon Poly +4 Neutral 32 mm ID Liners	
Cat. No.	OD (mm)
1219-32-448	48
1219-32-450	50
1219-32-452	52
1219-32-454	54
1219-32-456	56
1219-32-458	58
1219-32-460	60
1219-32-462	62
1219-32-464	64
1219-32-466	66

Pinnacle Marathon Poly +4 10 Degree 32 mm ID Liners	
Cat. No.	OD (mm)
1219-32-148	48
1219-32-150	50
1219-32-152	52
1219-32-154	54
1219-32-156	56
1219-32-158	58
1219-32-160	60
1219-32-162	62
1219-32-164	64
1219-32-166	66

Pinnacle Marathon Poly Lipped 32 mm ID Liners	
Cat. No.	OD (mm)
1219-32-252	52
1219-32-254	54
1219-32-256	56
1219-32-258	58
1219-32-260	60
1219-32-262	62
1219-32-264	64
1219-32-266	66

36 mm MARATHON CROSS-LINKED POLYETHYLENE LINER OPTIONS



Pinnacle Marathon Poly Neutral 36 mm ID Liners	
Cat. No.	OD (mm)
1219-36-056	56
1219-36-058	58
1219-36-060	60
1219-36-062	62
1219-36-064	64
1219-36-066	66

Pinnacle Marathon Poly +4 Neutral 36 mm ID Liners	
Cat. No.	OD (mm)
1219-36-452	52
1219-36-454	54
1219-36-456	56
1219-36-458	58
1219-36-460	60
1219-36-462	62
1219-36-464	64
1219-36-466	66

Pinnacle Marathon Poly +4 10 Degree 36 mm ID Liners	
Cat. No.	OD (mm)
1219-36-152	52
1219-36-154	54
1219-36-156	56
1219-36-158	58
1219-36-160	60
1219-36-162	62
1219-36-164	64
1219-36-166	66

ULTAMET METAL INSERT OPTIONS



Ultamet Metal Inserts 28 mm ID	
Cat. No.	OD (mm)
1218-89-148	48
1218-89-150	50
1218-89-152	52
1218-89-154	54
1218-89-156	56
1218-89-158	58
1218-89-160	60

Ultamet Metal Inserts 36 mm ID	
Cat. No.	OD (mm)
1218-87-352	52
1218-87-354	54
1218-87-356	56
1218-87-358	58
1218-87-360	60
1218-87-362	62
1218-87-364	64
1218-87-366	66

Note: Pinnacle Ultamet inserts must be used with the "M" specification femoral heads shown below.

"M" SPECIFICATION FEMORAL HEADS

Articul/eze 12/14 28 mm "M"	
Cat. No.	Neck Length
1365-11-500	+1.5
1365-12-500	+5.0
1365-13-500	+8.5

Articul/eze 12/14 36 mm "M"	
Cat. No.	Neck Length
1365-50-000	-2.0
1365-51-000	+1.5
1365-52-000	+5.0
1365-53-000	+8.5
1365-54-000	+12.0
1365-55-000	+15.5

S-ROM 11/13 28 mm "M"	
Cat. No.	Neck Length
1365-16-500	+0.0
1365-17-500	+3.0
1365-18-500	+6.0

S-ROM 11/13 36 mm "M"	
Cat. No.	Neck Length
1365-26-000	-3
1365-31-000	+0.0
1365-32-000	+3.0
1365-33-000	+6.0
1365-34-000	+9.0
* 1365-35-000 (skirted)	+12.0
1365-36-000 (Non-skirted)	+12.0

* This femoral head is indicated for use with polyethylene liners only.

AB GRIPPER INSERTER

Description	Part Number
2217-60-020	PINN AB INSERTER CASE COMPLETE
2217-60-021	PINN AB INSERTER TRAY
2217-60-022	PINN AB INSERTER LID
2218-90-000	AB STRAIGHT INSERTER
2218-90-001	PINNACLE 28MM TIP
2218-90-002	PINNACLE 36MM TIP
2218-90-003	AB CURVED INSERTER
2218-90-004	PINNACLE 40MM TIP
2218-90-005	PINNACLE 44MM TIP
2218-90-044	PINNACLE 44MM GRIPPER
2218-90-046	PINNACLE 46MM GRIPPER
2218-90-048	PINNACLE 48MM GRIPPER
2218-90-050	PINNACLE 50MM GRIPPER
2218-90-052	PINNACLE 52MM GRIPPER
2218-90-054	PINNACLE 54MM GRIPPER
2218-90-056	PINNACLE 56MM GRIPPER
2218-90-058	PINNACLE 58MM GRIPPER
2218-90-060	PINNACLE 60MM GRIPPER
2218-90-062	PINNACLE 62MM GRIPPER
2218-90-064	PINNACLE 64MM GRIPPER
2218-90-066	PINNACLE 66MM GRIPPER
2217-60-023	AB GRIPPER KIT PINNACLE

SCREW OPTIONS

Pinnacle 6.5 mm Cancellous Bone Screws	
Cat. No.	Length (mm)
1217-15-500	15
1217-20-500	20
1217-25-500	25
1217-30-500	30
1217-35-500	35
1217-40-500	40
1217-45-500	45
1217-50-500	50
1217-55-500	55
1217-60-500	60
1217-65-500	65
1217-70-500	70

Apex Hole Eliminator

Cat. No.	Description
1246-03-000	Apex Hole Eliminator

SHELL ALTERNATIVES



Pinnacle Porocoat 100 Shells	
Cat. No.	Size (mm)
1217-01-048	48
1217-01-050	50
1217-01-052	52
1217-01-054	54
1217-01-056	56
1217-01-058	58
1217-01-060	60
1217-01-062	62
1217-01-064	64
1217-01-066	66

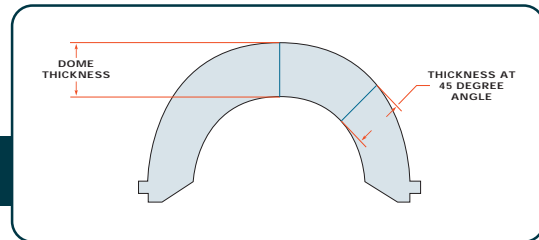
Pinnacle Porocoat Sector Shells	
Cat. No.	Size (mm)
1217-22-048	48
1217-22-050	50
1217-22-052	52
1217-22-054	54
1217-22-056	56
1217-22-058	58
1217-22-060	60
1217-22-062	62
1217-22-064	64
1217-22-066	66

Pinnacle 300 Shells	
Cat. No.	Size (mm)
1217-03-048	48
1217-03-050	50
1217-03-052	52
1217-03-054	54
1217-03-056	56
1217-03-058	58
1217-03-060	60
1217-03-062	62
1217-03-064	64
1217-03-066	66

Pinnacle Multi-Hole Shells	
Cat. No.	Size (mm)
1217-20-048	48
1217-20-050	50
1217-20-052	52
1217-20-054	54
1217-20-056	56
1217-20-058	58
1217-20-060	60
1217-20-062	62
1217-20-064	64
1217-20-066	66

Pinnacle HA 100 Shells	
Cat. No.	Size (mm)
1217-11-048	48
1217-11-050	50
1217-11-052	52
1217-11-054	54
1217-11-056	56
1217-11-058	58
1217-11-060	60
1217-11-062	62
1217-11-064	64
1217-11-066	66

Pinnacle HA Sector Shells	
Cat. No.	Size (mm)
1217-12-048	48
1217-12-050	50
1217-12-052	52
1217-12-054	54
1217-12-056	56
1217-12-058	58
1217-12-060	60
1217-12-062	62
1217-12-064	64
1217-12-066	66



SPECIFICATIONS

Polyethylene Liner Thickness Chart

Shell Size		Neutral		+4 Neutral		+4 10-Degree Face-Changing		Lipped	
Head Size	Size (mm)	Dome (mm)	45 Degree (mm)	Dome (mm)	45 Degree (mm)	Dome (mm)	45 Degree (mm)	Dome (mm)	45 Degree (mm)
28 mm	48	6.7	6.4	9.5	8.1	9.5	8.1	6.7	6.4
	50	7.8	7.4	10.5	9.2	10.5	9.2	7.8	7.4
	52	8.1	8.0	11.5	10.2	11.5	10.2	8.1	8.0
	54	8.5	8.5	12.5	11.2	12.5	11.2	8.5	8.5
	56	9.5	9.5	13.5	12.2	13.5	12.2	9.5	9.5
	58	10.3	10.3	14.3	12.9	14.3	12.9	10.3	10.3
	60	11.0	11.0	15.0	13.7	15.0	13.7	11.0	11.0
	62	11.8	11.8	15.8	14.4	15.8	14.4	11.8	11.8
	64	12.5	12.5	16.5	15.2	16.5	15.2	12.5	12.5
66	13.3	13.3	17.3	16.0	17.3	16.0	13.3	13.3	
32 mm	48	n/a	n/a	7.5	6.1	7.5	6.1	n/a	n/a
	50	n/a	n/a	8.5	7.1	8.5	7.1	n/a	n/a
	52	6.9	6.5	10.8	8.3	10.8	8.3	6.9	6.5
	54	7.9	7.4	11.8	9.3	11.8	9.3	7.9	7.4
	56	8.3	8.0	12.2	10.2	12.2	10.2	8.3	8.0
	58	8.3	8.3	12.4	11.0	12.4	11.0	8.3	8.3
	60	9.0	9.0	13.1	11.8	13.1	11.8	9.0	9.0
	62	9.8	9.8	13.9	12.5	13.9	12.5	9.8	9.8
	64	10.5	10.5	14.6	13.3	14.6	13.3	10.5	10.5
66	11.3	11.3	15.4	14.0	15.4	14.0	11.3	11.3	
36 mm	52	n/a	n/a	7.5	6.2	7.5	6.2	n/a	n/a
	54	n/a	n/a	8.5	7.2	8.5	7.2	n/a	n/a
	56	6.2	6.0	9.5	8.2	9.5	8.2	n/a	n/a
	58	6.9	6.7	10.3	8.9	10.3	8.9	n/a	n/a
	60	7.5	7.3	11.0	9.7	11.0	9.7	n/a	n/a
	62	7.7	7.7	11.8	10.4	11.8	10.4	n/a	n/a
	64	8.5	8.5	12.5	11.2	12.5	11.2	n/a	n/a
	66	9.2	9.2	13.3	11.9	13.3	11.9	n/a	n/a

There is a minimum of 6 mm of polyethylene thickness in the load-bearing area of all Pinnacle liners.

Pinnacle Acetabular Cup System and Ultamet Essential Product Information

Important: This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications: Total Hip Arthroplasty (THA) is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. THA is indicated for a severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previous hip surgery; and certain cases of ankylosis.

Pinnacle Acetabular Cups are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques. For metal-on-metal articulation, Pinnacle Acetabular Inserts are intended for use only with DePuy 28mm and 36mm Co-Cr-Mo femoral heads labeled for metal-on-metal use. Inserts with a 28mm inner diameter should be used with 28mm femoral heads only. Inserts with a 36mm inner diameter should be used with 36mm femoral heads only.

Contraindications: THA is contraindicated in cases of: active local or systemic infection; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; poor bone quality; Charcot's or Paget's disease; for hemi-hip arthroplasty – pathological conditions of the acetabulum that preclude the use of the natural acetabulum as an appropriate articular surface.

Use of Pinnacle Acetabular Inserts is contraindicated in cases with active or recent joint sepsis, insufficient bone stock, marked atrophy or deformity in the upper femur, skeletal immaturity, or where loss of musculature or neuromuscular disease would render the procedure unjustifiable.

Warnings and Precautions: Components labeled for "Cemented Use Only" are to be implanted only with bone cement.

The following conditions tend to adversely affect hip replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, history of infections, severe deformities leading to impaired fixation or improper positioning, tumors of the supporting bone structures, allergic reactions to materials, tissue reactions, and disabilities of other joints.

Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental or occupational conditions will likely result in extreme stresses to the implant may result in premature failure due to loosening, fracture or wear.

Do not mix inserts and shells from different systems. Pinnacle Acetabular Cup Inserts can be used only with Pinnacle Acetabular Shells. Use of components other than those recommended could lead to loosening, wear, fracture during assembly and premature failure.

The inner diameter of the insert must correspond to the hip head size. Use of an insert with a non-matching hip head size (e.g. 28mm inner diameter insert with a 22mm head) will result in accelerated wear and early failure. Metal-on-metal articulation must utilize DePuy head especially designed for this purpose.

The highly polished bore of the insert should not come into contact with abrasive surfaces, as this may damage the bore and affect performance. In addition, all mating surfaces should be clean before assembly to ensure proper seating. If the insert is not properly seated into the metal on metal shell it may become loose.

Adverse Events: The following are the most frequent adverse events after hip arthroplasty: change in position of the components, loosening of components, fracture of components, dislocation, infection, peripheral neuropathies, tissue reaction.

Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements. Subclinical nerve damage has also been reported more frequently, often associated with surgical trauma. Dislocation and subluxation resulting from improper positioning and/or muscle and fibrous tissue laxity may also occur, as may loosening and subsequent failure of the total hip prosthesis.

Rev 24 August 2006

IFU 0902-00-701, Rev. G – IFU, Total Hip Prosthesis

IFU 780-04-780, Rev. C – DePuy Pinnacle Acetabular Metal Inserts

US Patent 5,282,864; 6,316,158; 6,281,264; 6,242,507; 6,228,900; 6,017,975.

For more information about the Pinnacle Acetabular Cup System or alternative bearings, visit our web sites at www.jnjgateway.com/pinnacle or www.jnjgateway.com/aboutalternativebearings.



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