Shalby Advanced Technologies, Inc.

Restoring Mobility, Improving Lives.

Surgical Technique
Direct Anterior Approach

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INDICATIONS AND USAGE

The Shalby Advanced Technologies, Inc., Direct Anterior Approach instrumentation and surgical technique are designed for use with the TaperSet™ Hip System, which is comprised of TaperSet™ line of femoral stems and compatible femoral head and acetabular components of the Consensus Hip System, including Consensus Hip System sub-family of CS2™ Acetabular Cup System. The indications for use can be found in the IFU and are included here for reference.

The indications for use for TaperSet™ Hip System for Direct Anterior Approach are:

The TaperSet™ Hip System is designed for total hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System including the CS2™ Acetabular Cup System.

The indications for use are:

A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
C. Proximal femoral fractures.
D. Avascular necrosis of the femoral head.
E. Non-union of proximal femoral neck fractures.
F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The TaperSet™ hip stem is indicated for cementless use.

The Consensus acetabular cup components are intended for cemented or cementless use. The CS2 Ti plasma coated acetabular shell is intended for cementless use. The Consensus all-poly acetabular cup is intended for cemented use.

Instructions for use for Enztec manufactured items can be found on the Enztec website at the following address: https://www.enztec.com/ifu.

A surgeon must always rely on their own professional clinical judgement when deciding whether to use a particular product and surgical technique when treating a particular patient. Shalby Advanced Technologies, Inc., does not dispense medical advice and recommends that surgeons be trained in the use of any particular product or technique before using it in surgery. The surgeon should refer to the appropriate product package inserts for complete warnings, precautions, indications, contraindications and adverse effects, prior to using these systems.

Special thanks to the following surgeons for their contributions to this surgical technique:

Dr. Wesley Clark

Dr. Garen Collett

Dr. Ramneek Mahajan

Dr. Kyle McGivern

Dr. Mario Quesada

Dr. David Ryan

Dr. Justin Sherfey

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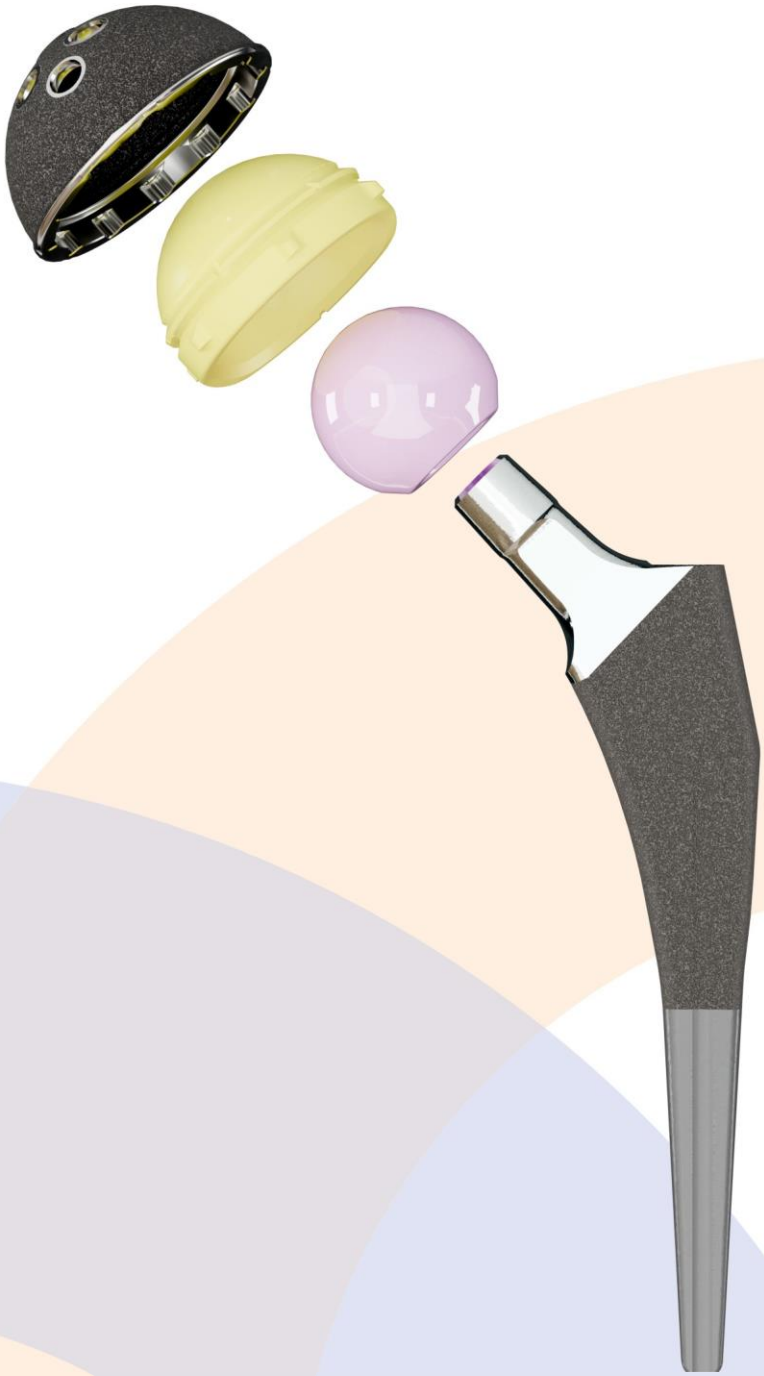

Direct Anterior Approach

Surgical Technique

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Surgical Technique

Pre-Operative Planning

It is important to plan the procedure preoperatively in order to select the correct implant type and size, and its final intraosseous position based on the patient's individual anatomy. The surgeon should perform a careful evaluation of the patient's clinical condition and consider multiple clinical factors, including the level of physical activity, before performing a hip replacement.

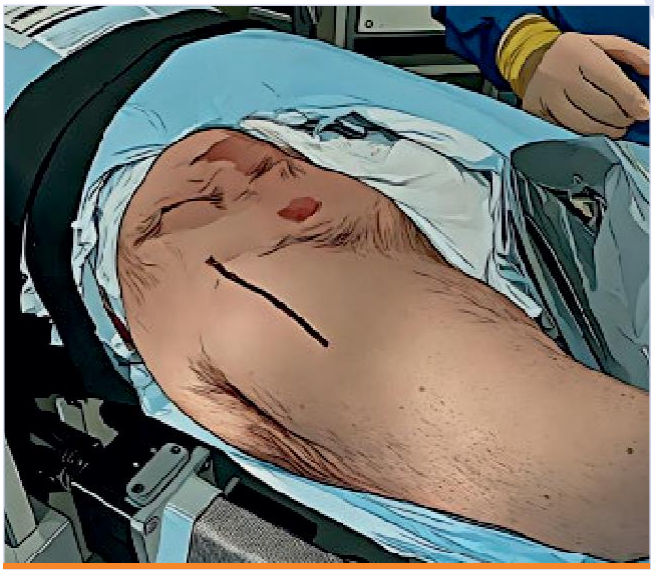
Patient Positioning

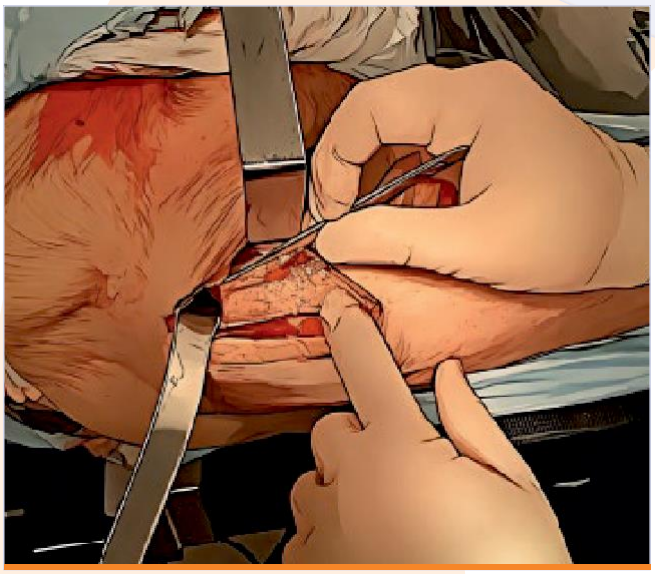
The patient is positioned in the supine position on either a special table (Hana, etc.) or standard operative table, based on surgeon preference, with standard anterior hip arthroplasty draping. Support the opposite non-operative hip close to the top of the greater trochanter to create a stable pelvis position. The patient should be positioned such that the trochanteric line is parallel to the breaking axis of the leg segment of the operation table. Care should be taken to ensure the correct pelvic tilt and rotation that mirrors the preoperative standing radiograph. Patient position on any style table should allow for fluoroscopy use during the case, if desired.

Planning & Skin Incision

If utilizing a traditional oblique longitudinal incision, palpate the greater trochanter and the anterior superior iliac spine (ASIS). Start the skin incision approximately 2-3 cm lateral and 2-3 cm cm distal from the ASIS. Extend the incision diagonally in-line with the fibers of the TFL and distally 2-3 cm below the greater trochanter, directed toward the head of the fibula or lateral epicondyle. After the initial skin incision, divide the subcutaneous tissue in line with the incision. There will be two thin fascial layers that continue from the abdominal layers of the Scarpa's and Camper's fascia. The TFL will be evident by a muscular tint under a thicker facial layer.

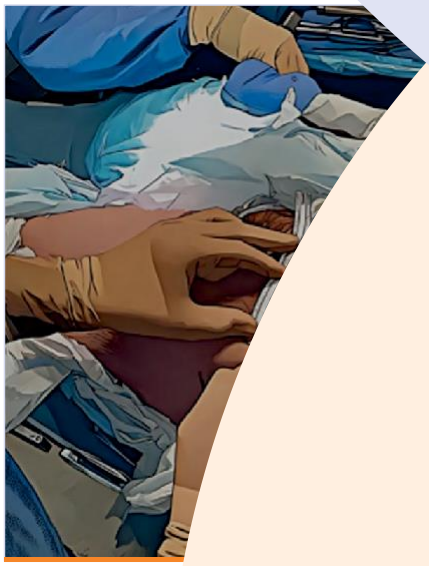
Tip: It is often helpful to identify the TFL muscle belly by its relatively thin fascial covering (allowing visualization of the muscle fibers) and the ubiquitous presence of perforating blood vessels.





To avoid damaging the lateral femoral cutaneous nerve (LFCN), stay lateral from the interval between the tensor fascia latae (TFL) and the sartorius muscle.

If utilizing a bikini incision, palpate the greater trochanter and ASIS and mark their position. Palpate the TFL and approximate location of the Smith-Peterson interval and mark their location. Mark the line for the bikini incision parallel to the inguinal crease, approximately 3 to 4 finger widths distal to the ASIS. The orientation of the line should be approximately perpendicular to that of a standard oblique longitudinal incision. The location of the incision relative to the femoral neck can be verified with fluoroscopy using a thin radiopaque object such as a small drill bit as a pointer.



Beginning just anterior and proximal to the tip of the greater trochanter, create an incision 8-10cm in length along the previously marked bikini incision line. Make the initial incision through the skin and down to the level of the subcutaneous fatty tissue.

Electrocautery can be used to coagulate any superficial bleeding vessels as needed. Continue through the subcutaneous fatty tissue through a narrow interval down to the level of the TFL fascia.

To help avoid damaging the LFCN, dissection should be kept in the lateral 2/3 of the incision.

Open the subcutaneous tissue to expose the fascia overlying the center of the TFL muscle belly utilizing Hibbs or Army-Navy style retractors or manually utilizing finger pressure. This should allow for similar visualization and exposure of the TFL as in a standard oblique longitudinal incision.

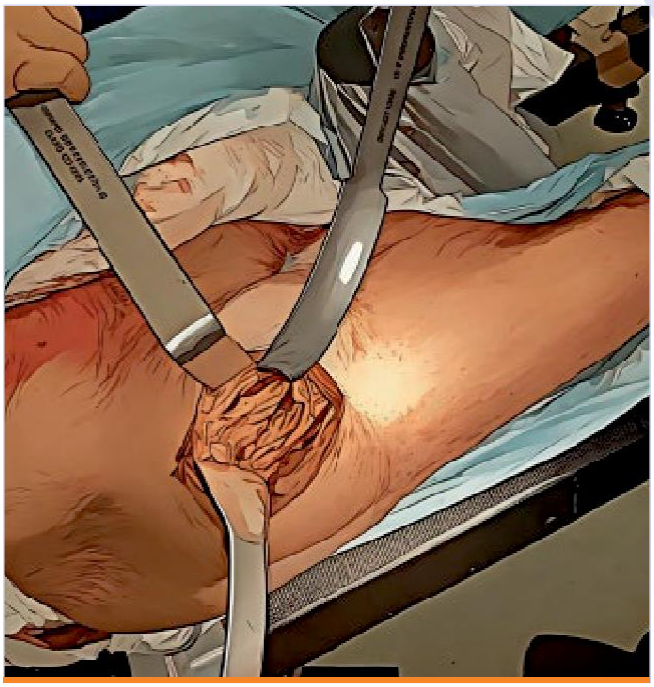
Tip: It is often helpful to identify the TFL muscle belly by its relatively thin fascial covering (allowing visualization of the muscle fibers) and the ubiquitous presence of perforating blood vessels.

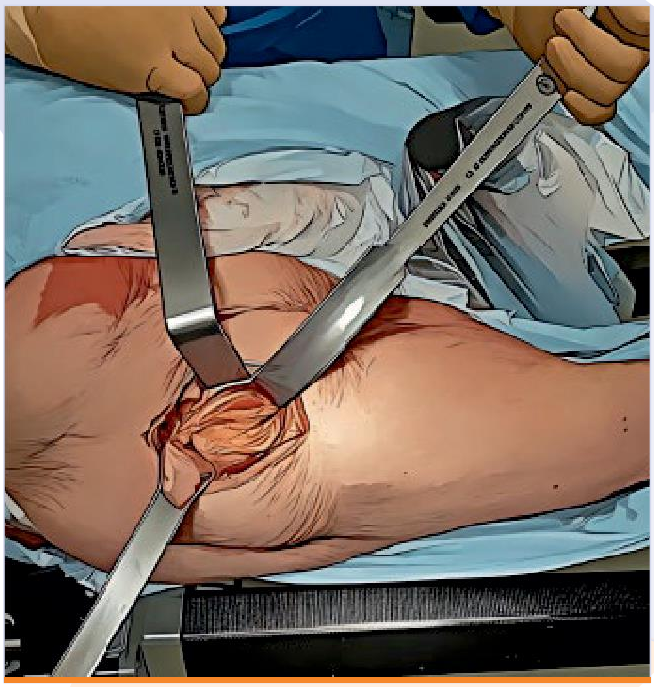
Capsular Exposure

Incise the fascia of the TFL just lateral to the junction with the sartorius in-line with the fibers of the muscle. Bluntly dissect the fascia from the TFL and gently pull the TFL laterally to identify the Smith Peterson interval. Palpate and enter the interval between the TFL and the sartorius muscle with your finger staying in the sheath of the TFL. Incise the deep investing fascia of the TFL and carefully identify and ligate the circumflex vessels while doing so. The circumflex vessels are typically found deep to the deep investing fascia of the TFL.

Place a standard Blunt Hohmann or Blunt Cobra retractor deep to the gluteus medius and minimus musculature over the capsule and over the superolateral part of the femoral neck. Incise the deep fascia between the rectus femoris and the TFL. Remove the fat pad under the rectus femoris which will reveal the anterior capsule. A Cobra Retractor, Standard Blunt or other type, can be placed deep to the rectus femoris over the capsule on the medial side, proximal to the lesser trochanter.

Care must be taken to place the retractor deep to the rectus to avoid vascular injury.





If desired, place an additional 90 degree Sharp Cobra or Single Prong Acetabular retractor over the anterior rim of the acetabulum perpendicular to the inguinal ligament at the 12 o-clock position. Additionally, the interval beneath the ilio-capsularsi can be bluntly developed and a 4th retractor placed anterior to the acetabulum. This retractor should be aimed towards the opposite kidney and not directly across the surgical field. This will help to avoid damage to the neurovascular structures. This will allow for good exposure of the capsule.

Capsular Incision

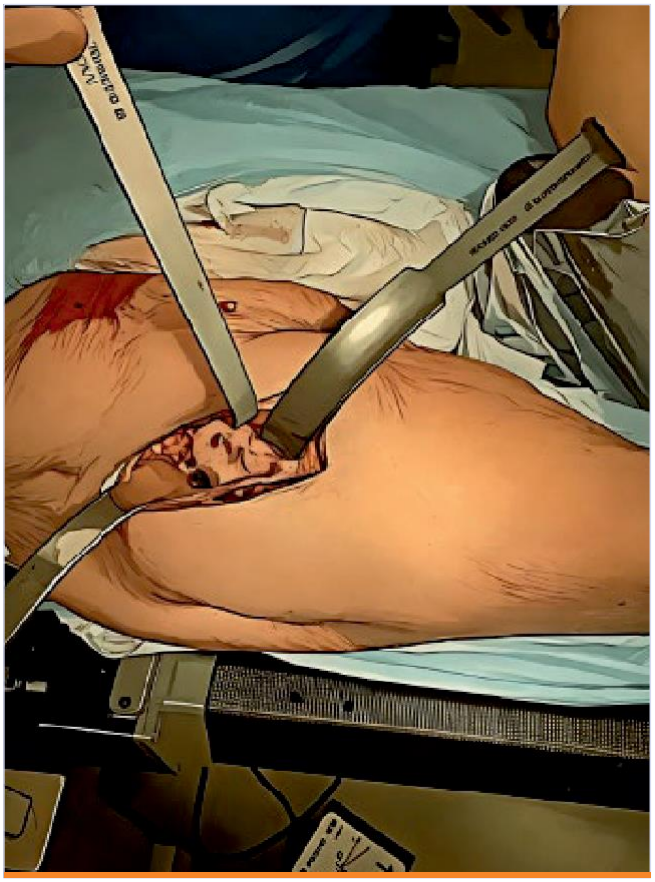
Different options exist to incise the capsule depending on anatomy and stiffness of the capsule. Perform an inverted T or H-shaped capsulotomy. Start your incision near the acetabulum and extend it to the intertrochanteric line in-line with the femoral neck.

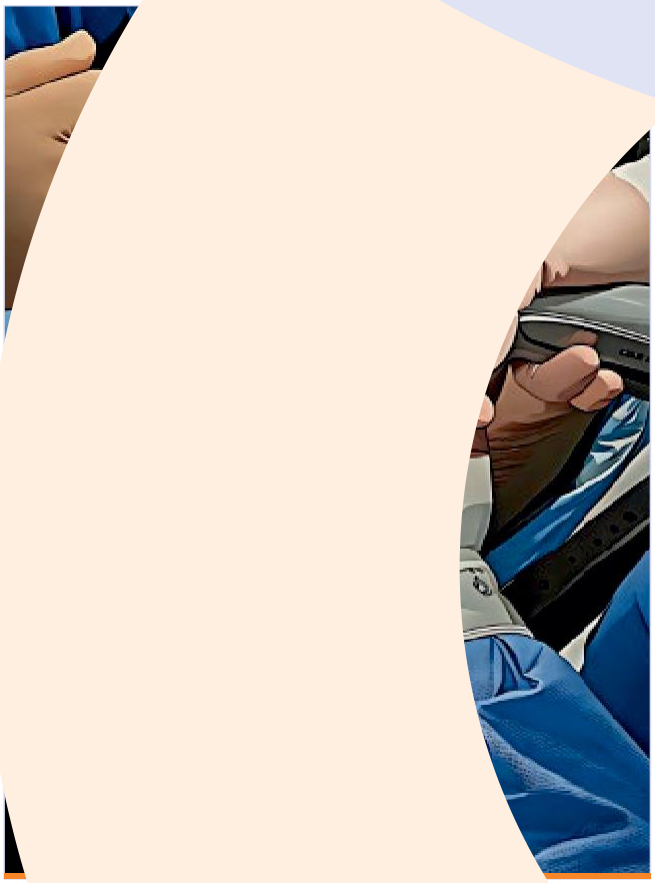
Alternatively, a capsulectomy can be performed based on surgeon preference.

Afterwards, reposition your retractors intracapsular on both sides of the femoral neck.

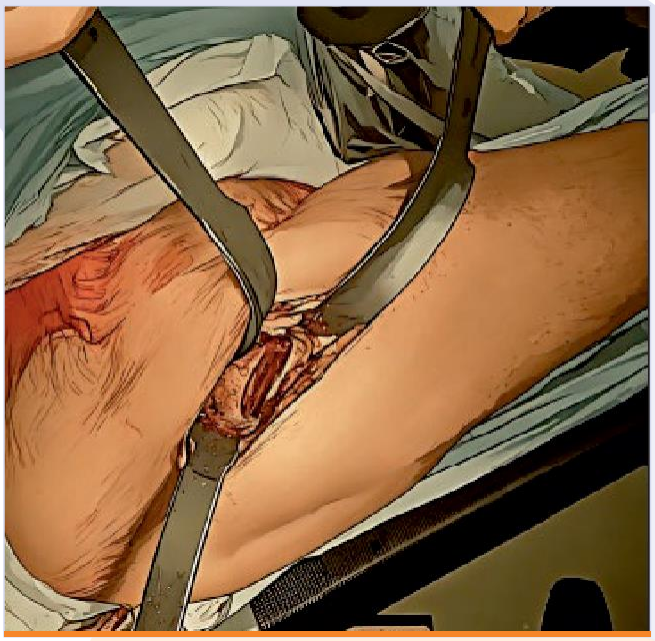
Removal of the Femoral Head

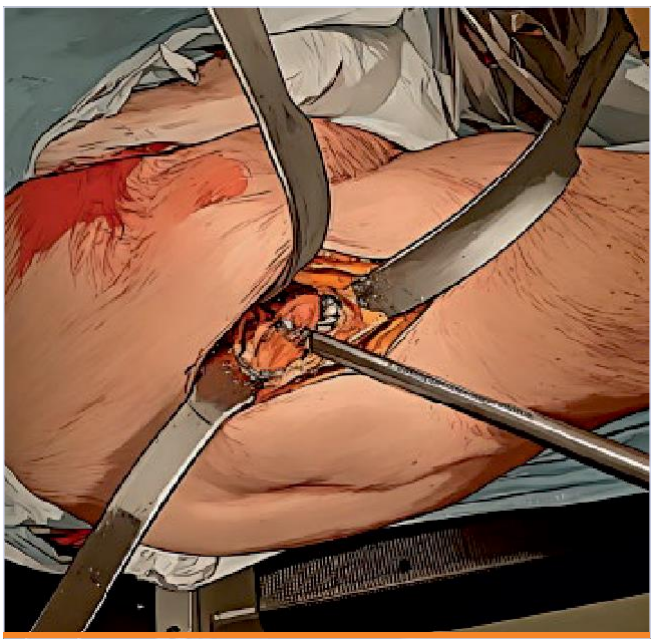
Mark the level of resection according to your preoperative planning or the planned femoral broach. Cut the femoral neck according to your marking. Removal of the femoral head can be facilitated by cutting and removing a slice of femoral neck (napkin ring). Perform the distal cut first and then the proximal cut second. Use the retractor to protect the muscle and soft tissue from the sawblade. Remove any anterior osteophytes from the acetabulum to aid in femoral head removal. Remove the femoral head with the Corkscrew Extraction instrument attached to the Modular T-Handle. Partial excision of the labrum and removal of antero-superior capsule may aid in removal of the femoral head. In addition, a femoral head slide or Cobb type elevator can be used to help with femoral head removal.

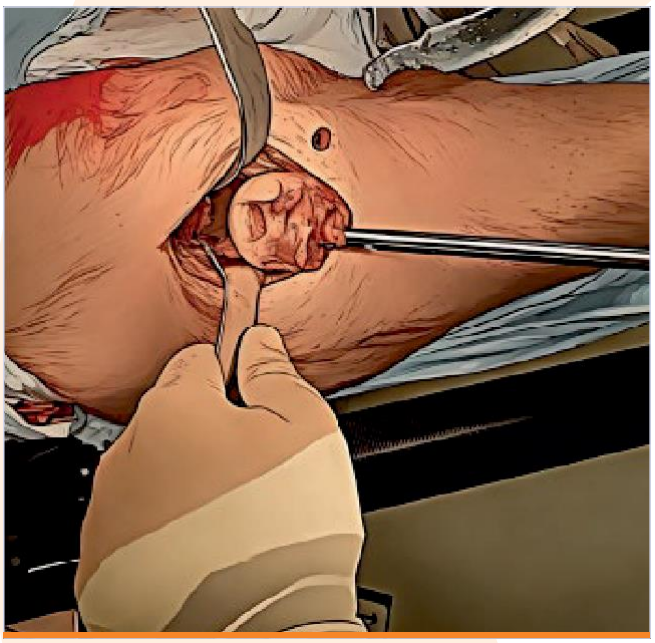




Tip: The single pronged retractor can be placed over the TAL in the inferior aspect of the acetabulum





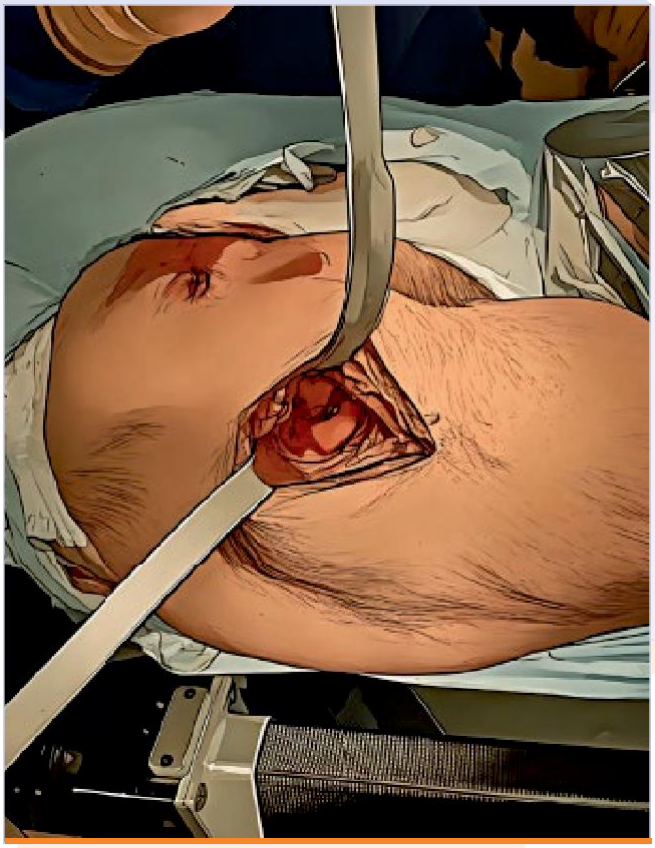


An alternate method of femoral head removal involves placing a corkscrew in the femoral head after the proposed incision is marked with an electrocautery. After the femoral neck cut is made, free movement of the corkscrew is indicative of a complete cut. Incomplete resection usually involves the inferior neck. Once the complete neck resection has been confirmed, the corkscrew can be used to lever the femoral head/neck against the proximal femur allowing for easy removal of the head.

The femoral head can be measured to help in estimating the size of the acetabular component.

Acetabular Exposure

Insert a Bent Hohmann retractor, Single Prong Acetabular Retractor or Whelan Hohmann Retractor over the labrum and anterior rim of the acetabulum. Place a Mueller retractor or other double prong retractor between the labrum and posterior capsule over the posterior rim of the capsule and directly on the bone. If desired, place an inferior acetabular retractor inferior to the transverse acetabular ligament to rest on the posterior ischial surface. This helps to retract the inferior soft tissues to facilitate acetabular reaming. Remove the remainder of the labrum.



The femoral nerve and psoas tendon are approximately 2 cm medial and 1 cm anterior to the anterior rim of the acetabulum, which can be damaged in case the retractor is placed in an incorrect way. Flexing the leg during insertion of the anterior retractor can serve to relax the soft tissues and nerve and make it safer to place the retractor. Do not place the retractor in soft tissues. It should be placed directly on the wall of the acetabulum.

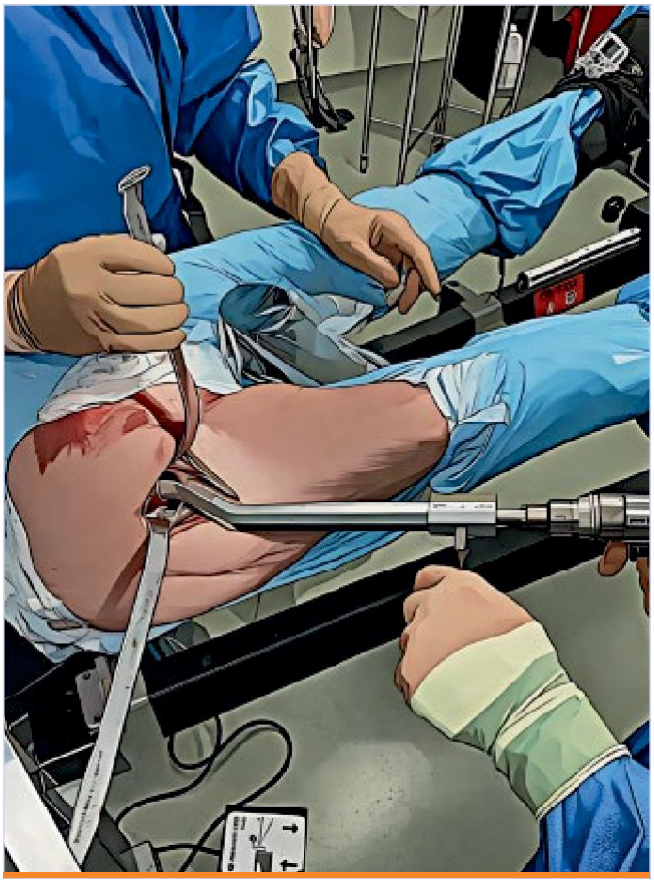
In addition, a single prong acetabular retractor, modified cobra, or long handle cobra retractor can be placed at the inferior acetabulum, just under the transverse acetabular ligament. Keep this along the bone on the inferior acetabulum. This will help retract soft tissue and facilitate exposure.

Alternatively, with the anterior acetabular retractor in place, an additional sharp retractor is placed beneath the TAL and a Mueller placed beneath the posterior rim of the acetabulum, which can be used to retract the proximal femur in a posterior direction.

Preparation and Reaming of the Acetabulum

Incise the dorsal capsule in the region directly posterior to the acetabulum. Place an additional Retractor (Mueller, Cobra, or other) at the posterior rim of the acetabulum (if not already in place).

Select the first reamer as described in the surgical technique for the CS2™ acetabular shell. Use the Offset Reamer Handle, if needed, to help avoid impingement with lateral tissue and excessive force against the anterior acetabular wall. Use care introducing and removing the reamer.



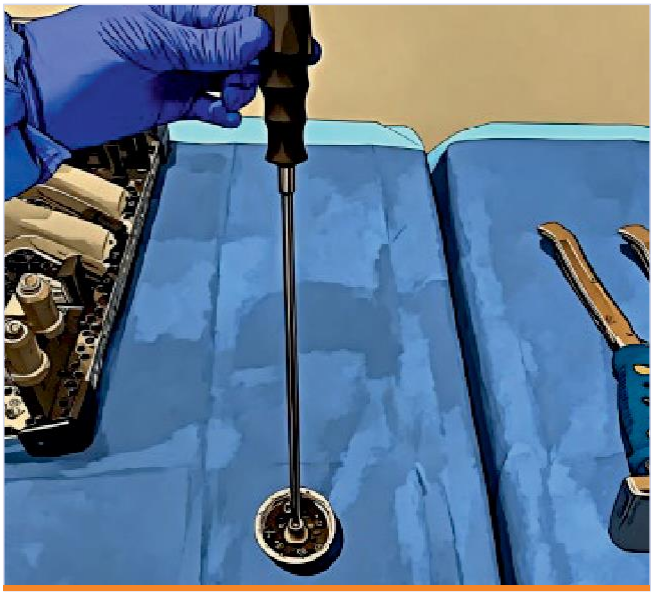
An alternative method may be used where the reamer is introduced by hand into the incision and then attached to the Offset Reamer Handle. The reamer may then be disengaged from the handle prior to removal.

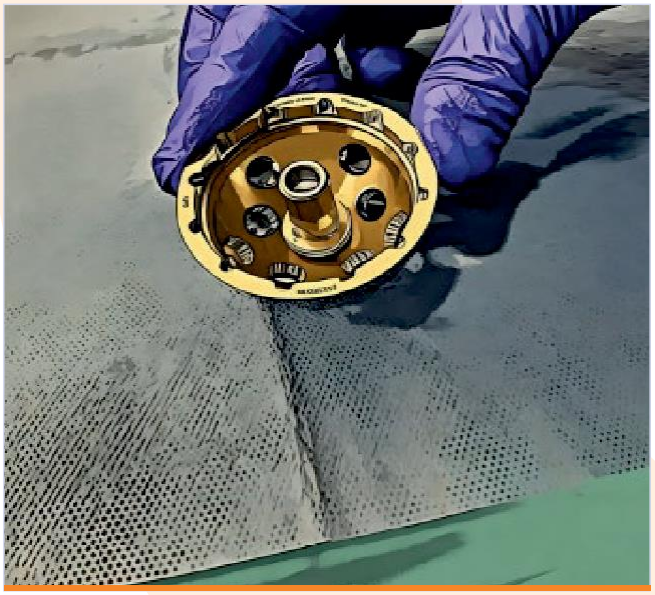
Ream the acetabulum using progressively larger reamers to the desired size as described in the CS2™ surgical technique.

Implantation of the Acetabular Cup

Tip: The position and size of an impacted trial shell can be confirmed with fluoroscopy to help determine size and position of the final implant.

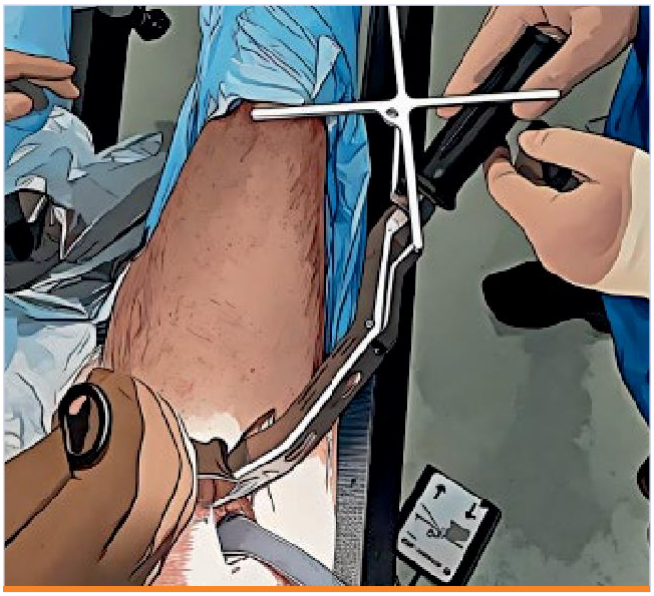
Attach the chosen size acetabular shell onto the Straight or Offset Cup Impactor handle and tighten. Care should be taken to position the screw holes in the proper orientation relative to the handle prior to final tightening. If utilizing the Enztec Offset Cup impactor, the threaded trinket can be attached separately to the shell and the assembly then attached to the handle by lifting the locking lever away from the body of the handle.

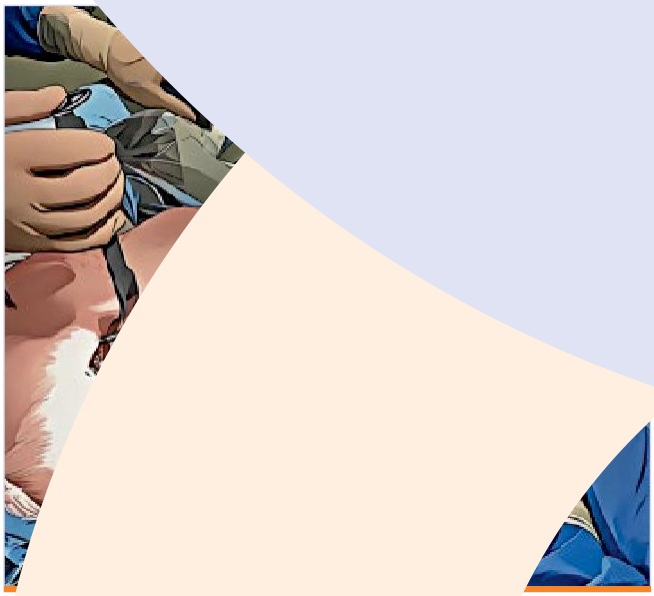




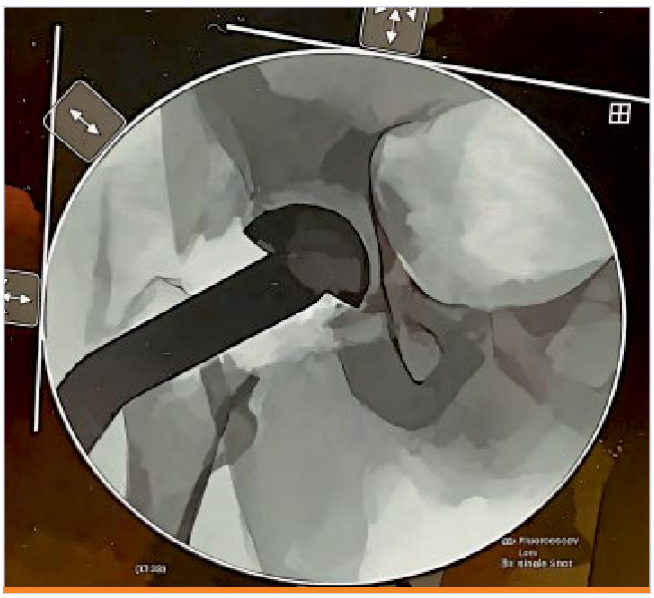
Attach the appropriate abduction/version alignment guide to the impactor handle (if desired).

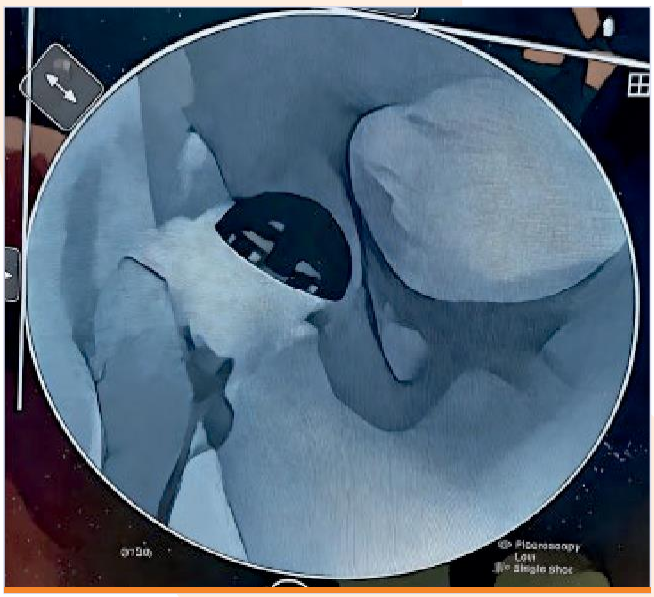
Insert the shell into the incision and adjust the orientation of the handle to achieve the desired alignment. Slight back and forth rotation can help clear soft tissue which may be impeding the cup from contacting the bone. Impact the cup into the prepared acetabulum in a manner consistent with the CS2™ surgical protocol. Care should be taken to avoid misdirected impaction and use of excessive force.

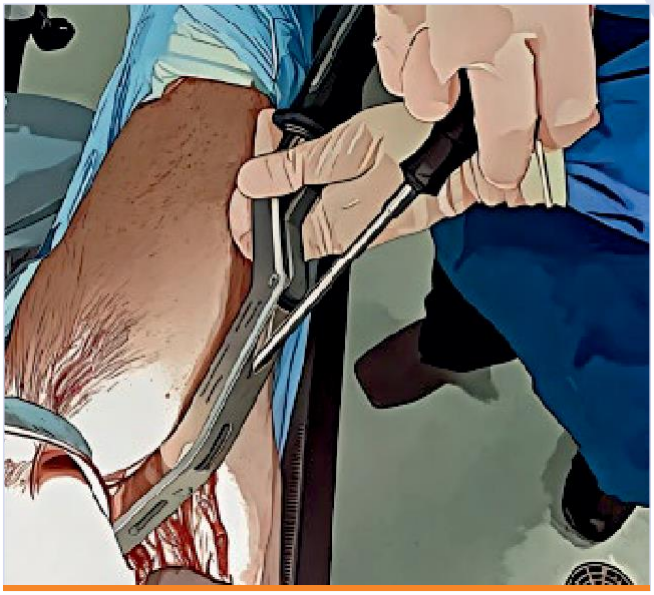




Proper alignment of the shell can be assessed radiographically prior to final impaction and disengagement of the impactor handle from the shell. If utilizing the Enztec Offset Cup impactor, the handle can be disengaged from the shell/trinket assembly by lifting the locking lever away from the body of the handle. This can aid in visualization during the radiographic assessment.



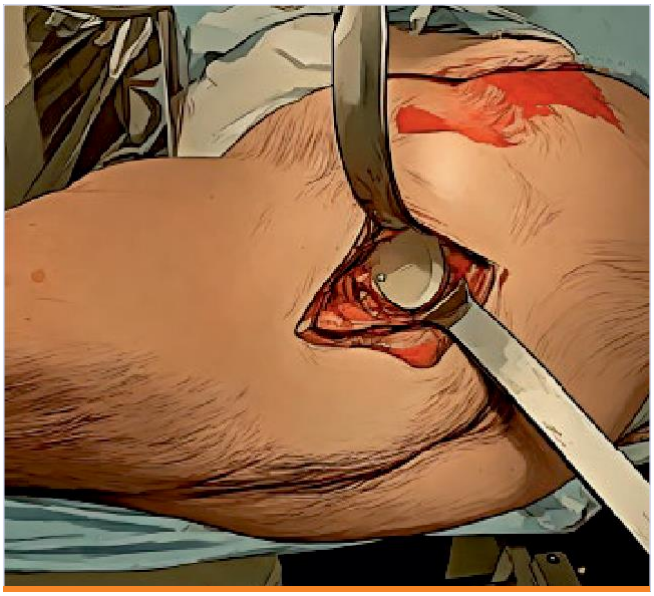


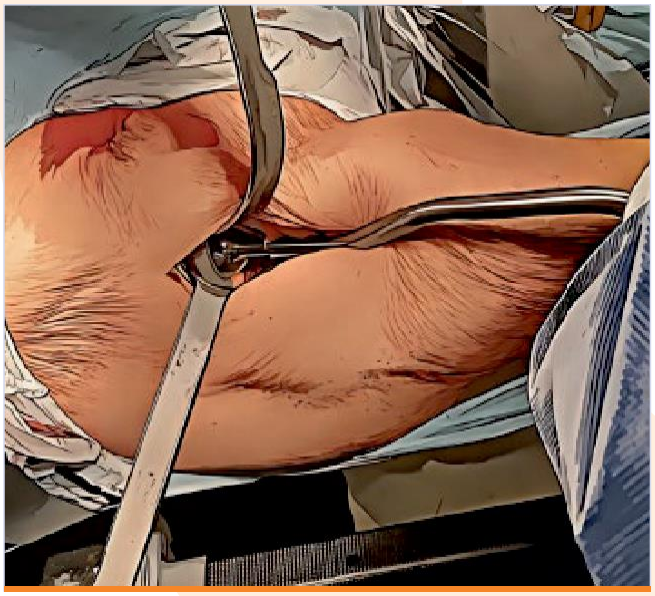


If implanting a CS2™ shell with screw holes, the holes should be placed in the superior aspect of the cup during insertion to insure proper screw placement if desired.

If screw fixation is desired, use a flexible drill and drill guide to prepare the holes as described in the CS2™ surgical protocol. Hole depth can be measured using the screw depth gauge. Use a flexible screwdriver to insert the screws. Care should be taken to ensure that the screws are fully seated in the shell prior to impaction of the chosen shell liner. Screw placement can also be confirmed with fluoroscopy.

Impaction of the liner can be accomplished at this point, if desired, using the Offset Liner Impactor and the appropriately sized Ball Attachment.





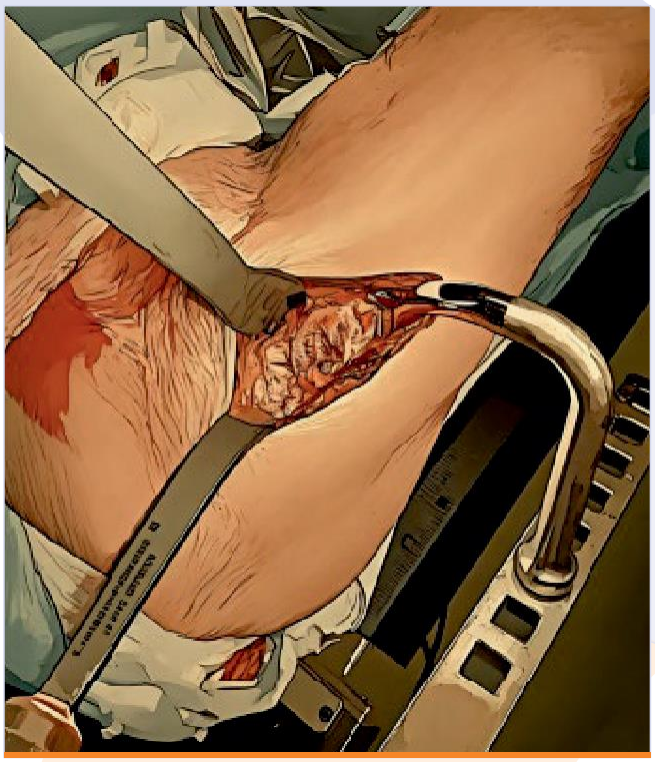
Positioning of the leg

Positioning of the leg is a very important step for femoral exposure during the direct anterior approach. Leg position can vary significantly depending on the type of table used during the operation. Hyperextend the hip approximately 20 degrees by lowering the leg section of the operating table. Additionally, rotate the leg externally by 60 – 90 degrees with the knee flexed approximately 10 - 30 degrees. Adduct the operative leg to better expose the femoral neck.

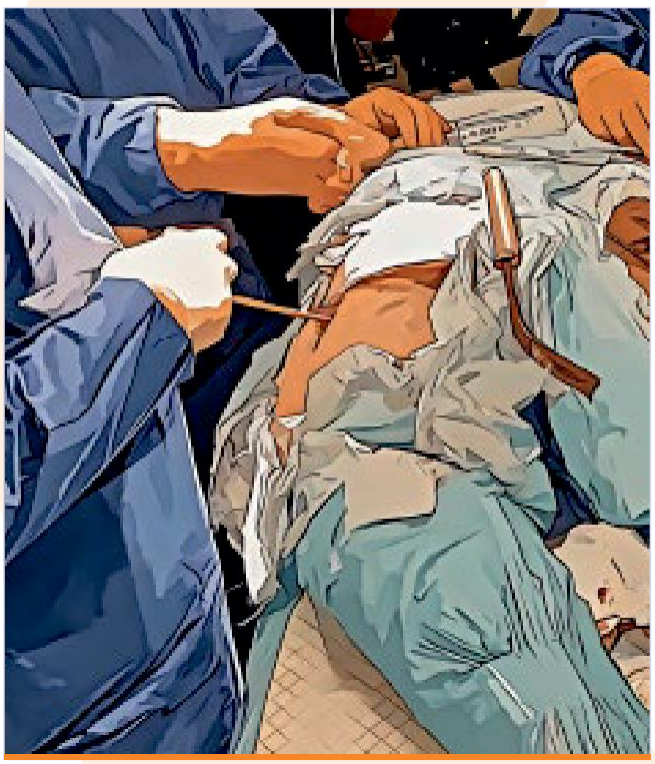
If utilizing a traditional table, an additional arm board can be placed on the contralateral end of the table to further facilitate leg adduction for femoral exposure. This ensures the contralateral leg does not fall off the table.

Femoral Exposure

Place a Double Prong Flared Cobra Retractor or Mueller Retractor around the postero-medial calcar and place a Modified Cobra Retractor or Mueller Retractor over the tip of the greater trochanter in-line with the axis of the femur.



To elevate the femur, release the superior portion of capsule from the neck osteotomy line to the top of the greater trochanter. A Bone Hook may be inserted into the calcar region of the femur to assist in elevating the femur. When utilizing the Bone Hook, counter levering should be applied with the Mueller retractor to minimize the forces exerted to the greater trochanter. Care should be taken not to release the piriformis tendon. The fat pad should now be visible.

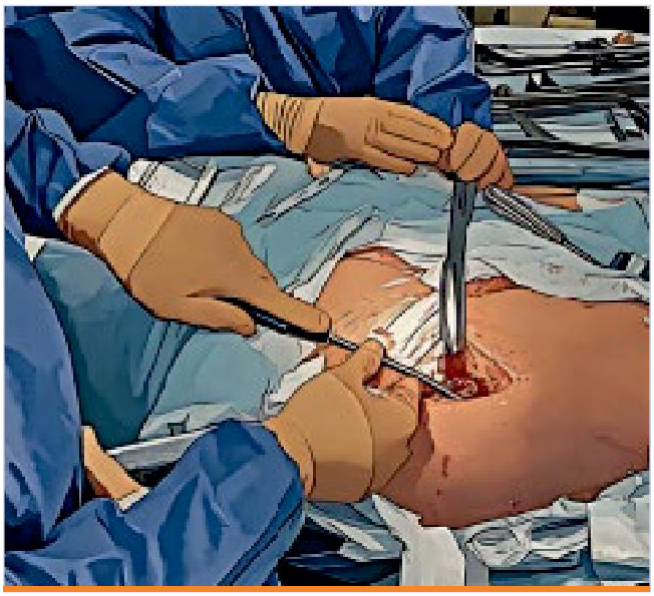


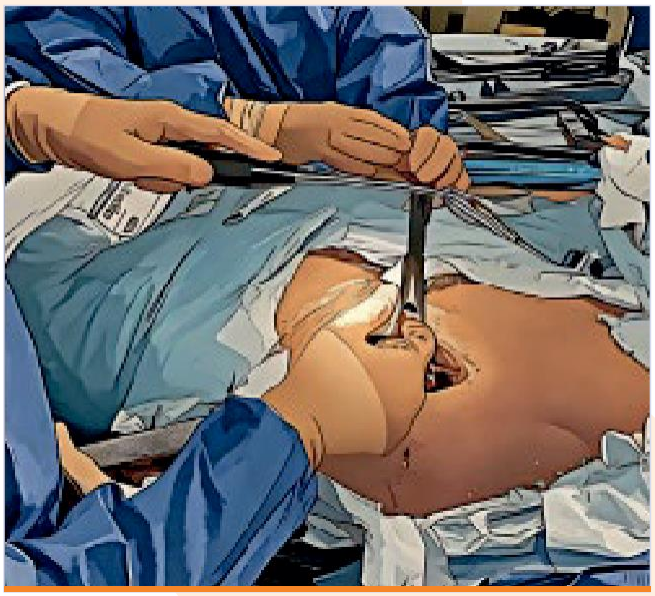
Tip: To facilitate femoral exposure the superior capsule needs to be released. This can be done by placing a bone hook in the proximal femur, pulling the femur anteriorly and laterally. A bovie can be used to release the superior capsule from the greater trochanter demonstrating elevation of the proximal femur and facilitating placement of a two-pronged retractor beneath the trochanter.

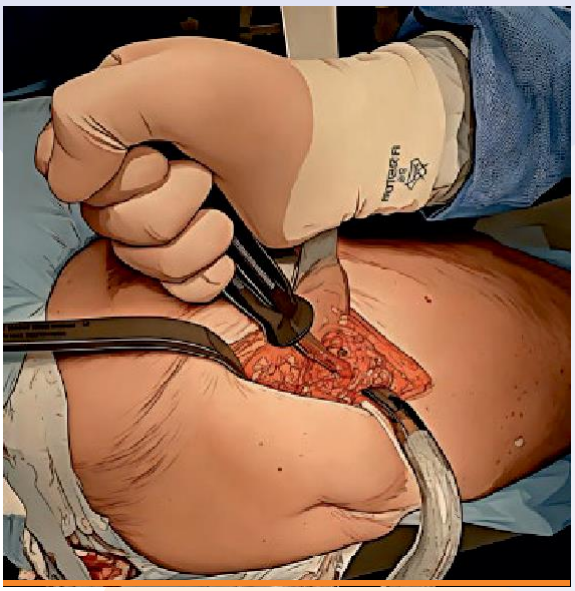
If using a standard operating table, the limb can be placed in a figure-of-4 position with the operative limb placed beneath the non-operative limb. This provides adduction and external rotation to assist with exposure. A broad 2-pronged retractor is placed beneath the greater trochanter and a second retractor is placed medial to the proximal femur to assist with soft-tissue retraction.

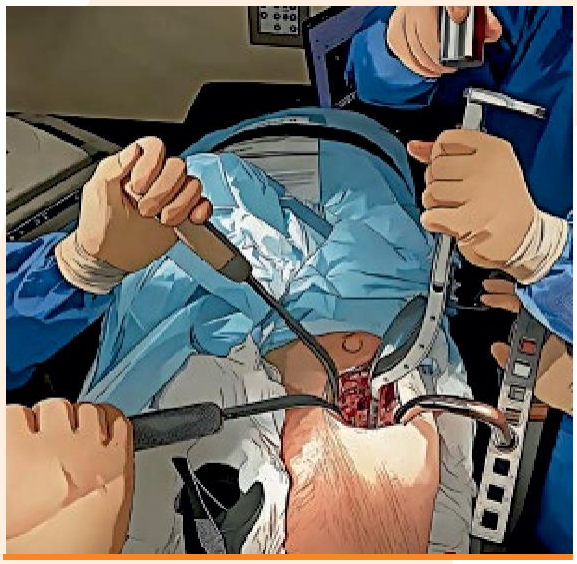
Opening the Femoral Canal

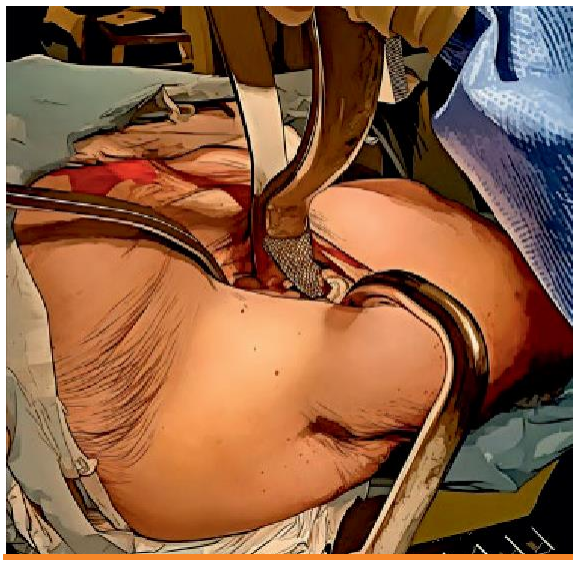
The femoral canal may be opened and directionally verified using the Angled Curette. Use a rongeur or the Modular Box Chisel to remove bone in the posteriolateral region of the femoral neck. The canal can be further exposed and cleared using a Curved Rasp, which can also aid in lateralization of subsequent steps. A modular Mini Broach can be used to begin the broaching in the planned version orientation. The Broach Rasp can be used to remove bone laterally in the canal, smooth any endosteal irregularities, and further help prevent varus positioning of the broaches.





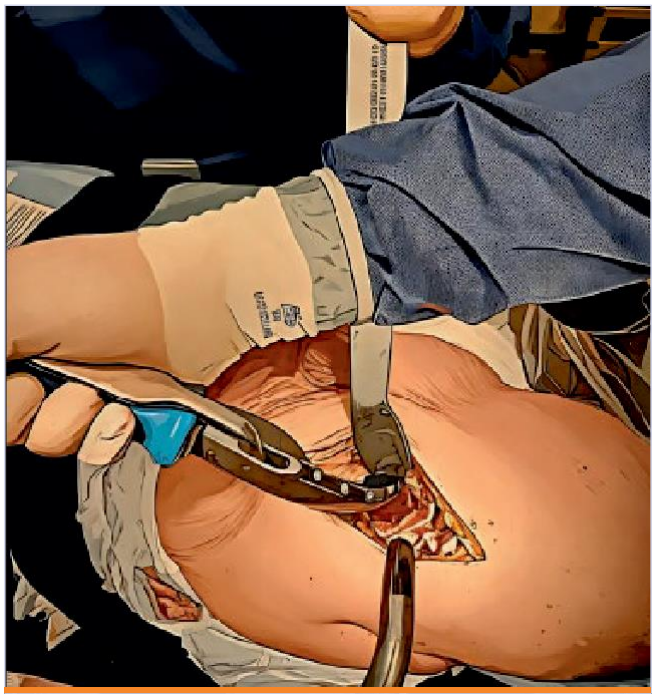


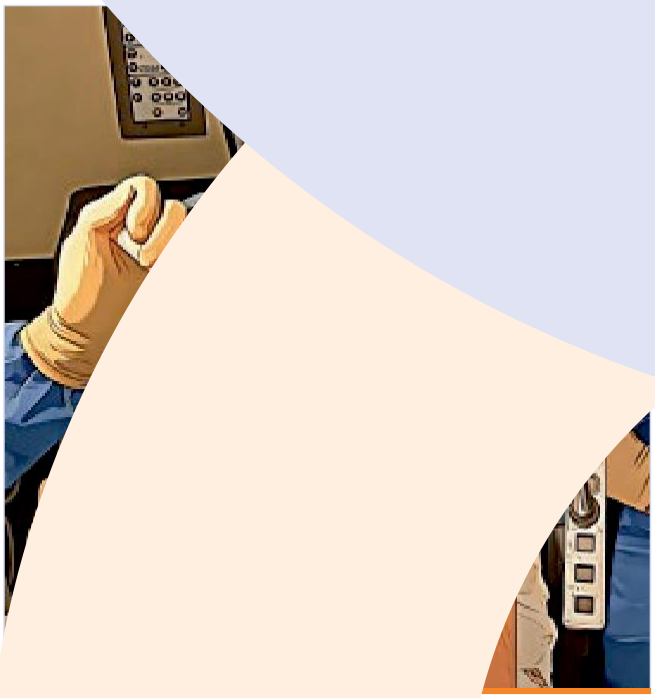


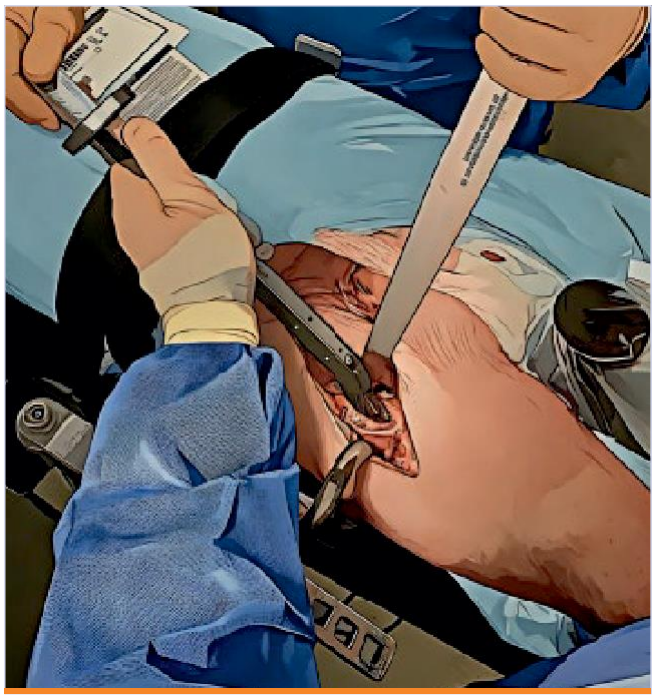


Broaching the Femur

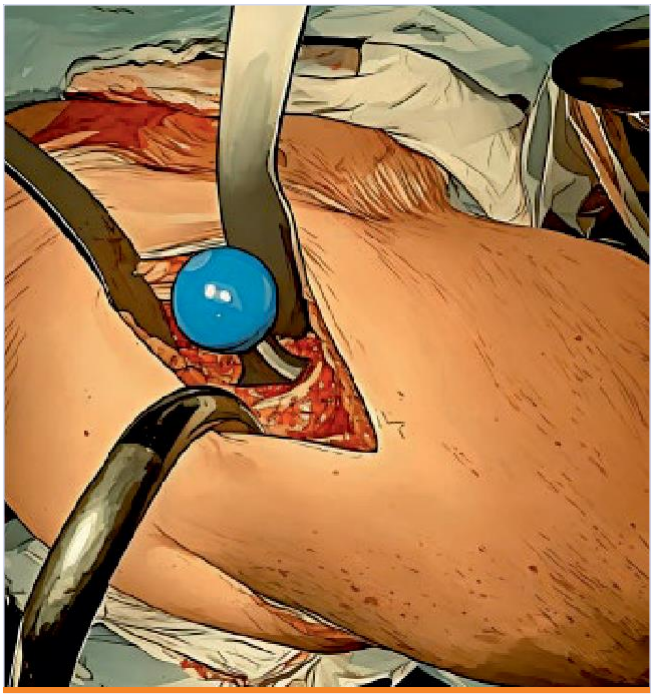
Dual Offset Broach Handles or straight broach handles may be used during the broaching process. Progressive broaching is performed until the desired sized broach is fully seated and has filled the proximal femur following the TaperSet™ surgical protocol.



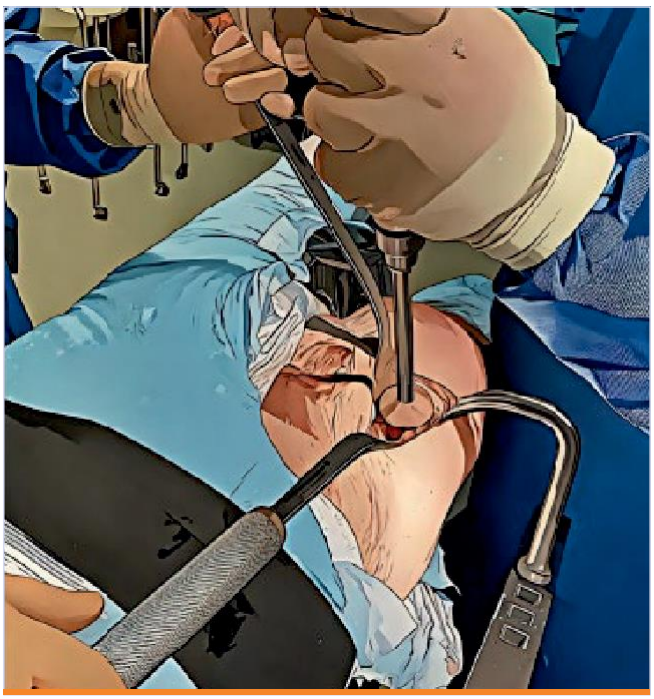




The final broach should be left in place to complete a trial reduction. Trialing is performed to confirm that leg length, range of motion and hip stability are satisfactory. Fluoroscopic imaging can be used to confirm the correct sizing and alignment of the stem. This can help to prevent undersizing or excessive varus orientation.

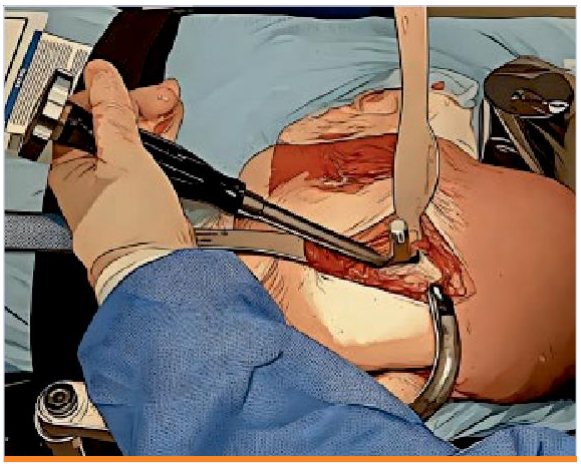


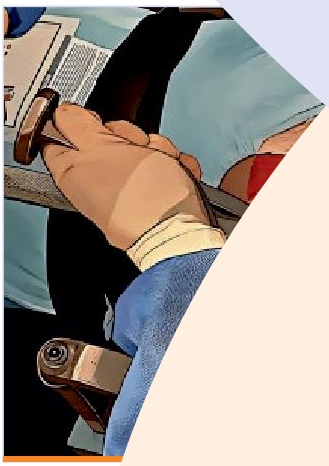
A calcar planer may be used on the final broach to remove any irregularities from the exposed surface of the resected femoral neck.



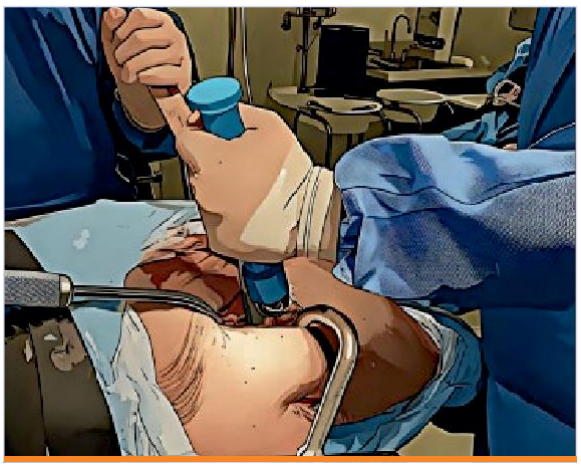
Implantation of the Femoral Implants

Introduce the femoral stem implant by hand into the broached cavity. The stem should sit within 1cm of the neck cut. If the stem is proud, check for soft tissue that has folded into the femoral canal. Using either the Straight or Offset Stem Impactor, advance the stem in a manner consistent with the TaperSet™ surgical protocol.





Once the stem has been fully seated, a final trial reduction can be accomplished with the appropriate size trial femoral head and/or trial acetabular liner if desired. Impact the femoral head onto the trunnion of the femoral stem using the Femoral Head impaction instrument. If not done previously, impact the liner into the acetabular shell using the Offset Liner Impactor and appropriately size ball attachment. Reduce the hip and confirm appropriate size and position of the final implants as well as leg length under fluoroscopy as desired.



Closure

Closure of the wound is performed in a manner familiar to the surgeon.

Instruments

Instrument Sets

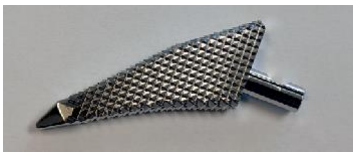
Individual Instruments		
Single Prong Acetabular Retractor	1080-0-0501 or 6570	
Whelan Hohmann Retractor	1080-0-0601 or 7116	
Bent Hohman Long Handle	1080-0-0901 or 7110-01	
Modified Cobra Retractor	1080-0-0201 or C1012	
Standard Cobra Retractor	1080-0-0101 or 6130	

Mueller Retractor Standard	1080-0-0701 or 3415	
Bone Hook Large	1080-0-1001 or 5920	
Hibbs Retractor Standard	1080-0-0801 or 6240	
Corkscrew Femoral Head Extractor	1080-0-1101 or 3706	
Angled Curette	1080-0-1201 or 5171	
Left Double Prong Flared Cobra Retractor	1080-0-0301 or 6110-02	

Right Double Prong Flared Cobra Retractor	1080-0-0401 or 6110-01	
Curved Canal Finder Rasp	1080-0-1301 or 3004-02	
Offset Acetabular Liner Impactor & Ball Attachments	1080-0-1401, 1402, 1403, 1404 or 5031 & 5202-28/32/36	
Left Double Offset Broach Handle	1080-0-1901 or 1080-0-2001 or OP0228L, or OP0395L or 4251-4180	
Right Double Offset Broach Handle	1080-0-1902 or 1080-0-2002 or OP0228R, or OP0395R or 4251-4181	
Offset Acetabular Reamer Handle	1800-0-2210 or 1080-0-1801 or 4250-7050 or 50244502	

Offset Acetabular Shell Impactor & Trinket	1080-0-1701 & 1080-0-1502 or 4252-2420 & 4252-2448	
Offset Acetabular Shell Impactor Hex Driver	1080-0-1501 or 4252-2311	
Offset Shell Impactor Alignment Attachment	1080-0-1601 or 4252-2221	

Additional Existing Instruments

Modular Box Osteotome	1910-0-0002	
Modular Mini Broach	1910-1-0003	
Modular Curved Broach	1910-0-0001	
Modular T-Handle	0800-0-1600	
Offset Femoral Stem Impactor Monoblock	1910-1-0012	
Femoral Head Impactor	4410-20070-A	

References

- CS2™ Cup System Surgical Technique – 98049-01, Shalby Advanced Technologies, Inc.
- TaperSet™ Hip System Surgical Technique – 98057-01, Shalby Advanced Technologies, Inc.