HEALTHCARE

Transition

HIP IMPLANT SYSTEM

(Uncemented)

PRODUCT MANUAL

Transition Hip Femoral Stem

Made of Ti-6Al-4V alloy as per ISO 5832-3 and ASTM F 136

Sl.No.	Ref. No.	Size	Stem Length (mm)	Offset (mm)	Neck Shaft Angle
1	ATFHSCL00	0	115	38.1	135°
2	ATFHSCL01	1	130	38.7	135°
3	ATFHSCL02	2	140	38.8	135°
4	ATFHSCL03	3	145	40	135°
5	ATFHSCL04	4	150	40.8	135°

Transition Hip Femoral Head

Made of Co-Cr alloy as per ISO 5832-4 and ASTM F 75

Sl.No.	Ref. No.	Diameter (mm)	Head Offset (mm)
1	ACHFH28N4	28	-4
2	ACHFH28S0	28	Standard
3	ACHFH28P4	28	4
4	ACHFH28P8	28	8
5	ACHFH32N4	32	-4
6	ACHFH32S0	32	Standard
7	ACHFH32P4	32	4
8	ACHFH32P8	32	8
9	ACHFH36N4	36	-4
10	ACHFH36S0	36	Standard
11	ACHFH36P4	36	4
12	ACHFH36P8	36	8

Transition Hip Acetabular Shell

Made of Ti-6Al-4V alloy as per ISO 5832-3 and ASTM F 136

Sl.No.	Ref. No.	Outer Diameter (mm)
1	AHASTPS44	44
2	AHASTPS46	46
3	AHASTPS48	48
4	AHASTPS50	50
5	AHASTPS52	52
6	AHASTPS54	54
7	AHASTPS56	56
8	AHASTPS58	58

Transition Hip Acetabular Liner

Made of Highly Cross Linked PE as per 5834-2 and ASTM F 648

Sl.No.	Ref. No.	Cup Diameter (mm)	Inner Diameter (mm)	Head Size to be Used
1	AHAL2844	44	28	28
2	AHAL2846	46	28	28
3	AHAL3248	48	32	32
4	AHAL3250	50	32	32
5	AHAL3252	52	32	32
6	AHAL3254	54	32	32
7	AHAL3256	56	32	32
8	AHAL3258	58	32	32
9	AHAL3652	52	36	36
10	AHAL3654	54	36	36
11	AHAL3656	56	36	36
12	AHAL3658	58	36	36

Transition Hip Cancellous Fixation Screw

Made of Ti-6Al-4V alloy as per ISO 5832-3 and ASTM F 136

Sl.No.	Ref. No.	Screw Size (mm)	Length (mm)
1	ACFS10	6.5	10
2	ACFS15	6.5	15
3	ACFS20	6.5	20
4	ACFS25	6.5	25
5	ACFS30	6.5	30
6	ACFS35	6.5	35
7	ACFS40	6.5	40
8	ACFS45	6.5	45
9	ACFS50	6.5	50

TK HEALTHCARE

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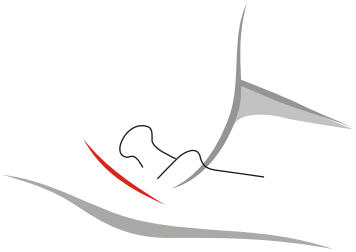
HIP IMPLANT SYSTEM

(Uncemented)

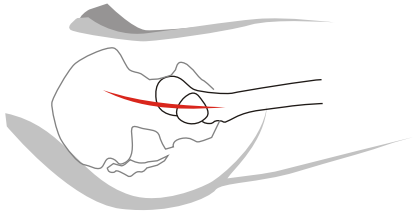
Surgical Technique

Surgical Approach

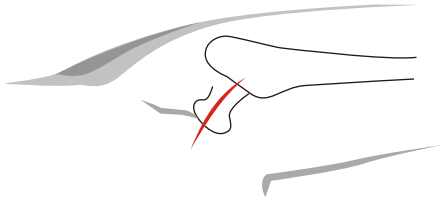
Transition stem can be used with any surgical approach such as Posterolateral approach, Anterolateral approach or Direct anterior approach. (Fig. 1, 2 & 3)



Posterolateral approach
Figure 1



Anterolateral approach
Figure 2



Direct-anterior approach
Figure 3

Femoral Neck Resection

The angle of resection should be 45 degrees. The neck resection guide should be used to determine the level of femoral neck resection. If the resection is too high, it may result in varus positioned stem. (Fig. 4)

Note: The osteotomy can be performed in one or two steps depending on the surgeon's preference.

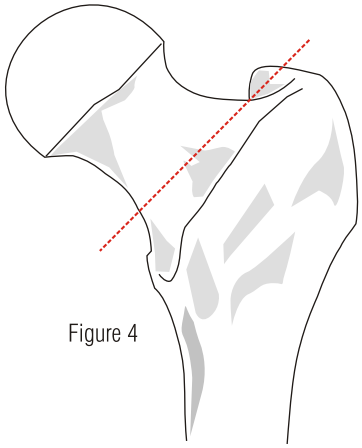


Figure 4

Proximal Cancellous Bone Compaction

It is important to select a point of entry posterolaterally to the Piriformis Fossa to avoid varus positioning. Use a curette or general instrument to indicate the direction of the canal. Use the bone tamp to compact the cancellous bone proximally. (Fig. 5)

To prevent under-sizing or varus positioning, the greater trochanter may be prepared with an osteotome to allow better insertion of broaches.

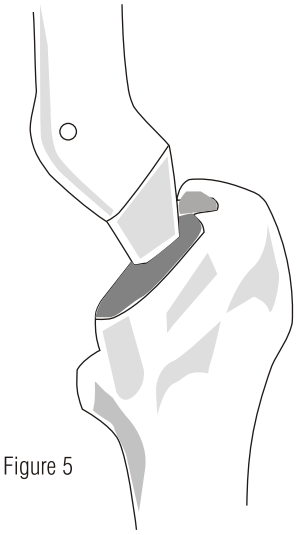


Figure 5

Acetabular Reaming

The goal of acetabular reaming is to restore the centre of the original acetabulum. Initially, employ a reamer 6 - 8 mm smaller than the anticipated acetabular component size. (Fig. 6 & 7). Subsequent reaming should proceed in 1 - 2 mm increments. Centre 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.

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.

In some patients, line-to-line reaming may be sufficient to achieve stability.

Where the acetabulam is reamed often determines where the cup will seat, it is important to ream where the final cup is to be positioned. As such a part of the reamer head will be visible on the superolateral rim when reaming (Fig. 7).

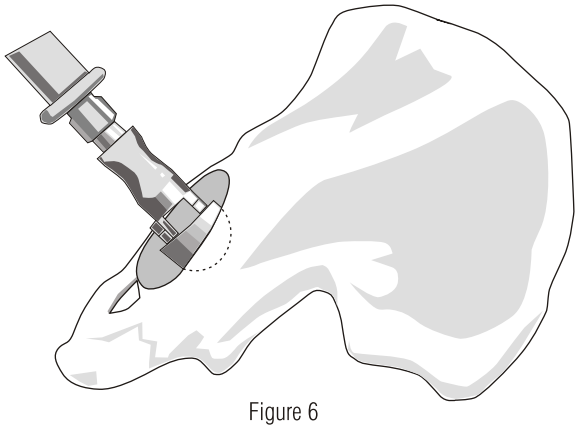


Figure 6
Acetabular reaming

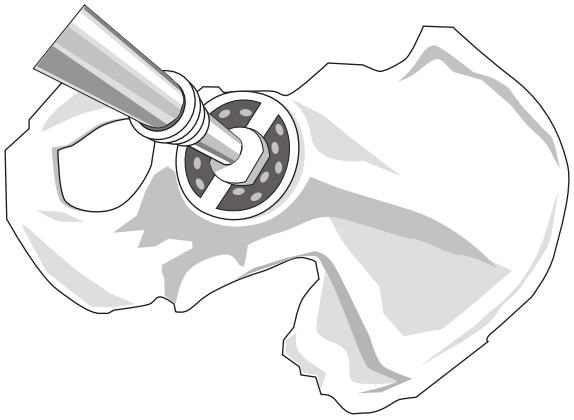


Figure 7
Acetabular reaming

Acetabular Cup Trialling and Positioning

Determining the Abduction Angle

The pre-operative A/P X-ray can help determine the ideal abduction angle (Fig.8) and be helpful in determining how much of the acetabular component should be left uncovered to provide the proper implant abduction angle (Fig.9).

The landmarks for acetabular component positioning are the medial wall of the acetabulam (the radiographic tear drop) and the lateral superior rim of the acetabulum.

Figure 8
Pre–operative determination of abduction angle

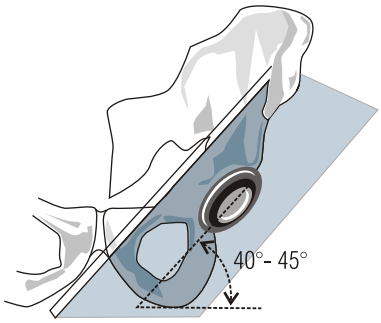


Figure 9
Cup abduction is typically 40°- 45°

Determining Proper Anteversion

A method for determining proper anteversion is the use of bony landmark or the transverse acetabular ligament. Other methoda 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 cup orientation. The cup should be slightly more anteverted than the pubis/ischial plane. This relationship should remain constant regardless of the depth of reaming. (Fig. 10 & 11)

Trial cups in 2 mm incremental sizes are available to assess cup fit and orientation. Select acetabular trial according to the final reamer size. Peripheral rim ridges on the trial cup enhance the stability of the trial cup through trial reduction. Select liner trials equal in diameter to trial cups. For example, a 54 mm polyethylene liner trial fits 54 mm trial cups. Using cup and liner trials in conjunction with the femoral component trials aids in ensuring optimum position of the components.

Figure 10
Pre–operative assessment of coverage of the acetabulum

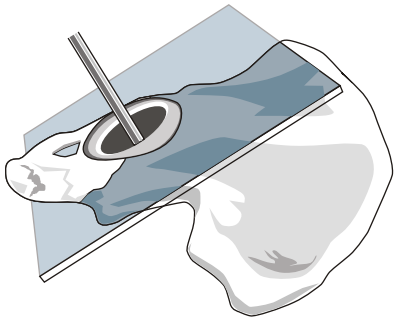


Figure 11
Cup anteversion is typically 15°-20°

Cup positioning should be varied to optimize fixation, range of motion and dislocation resistance and minimize the likelihood of subluxation, impingement and edge loading. This may be assessed during pre-operative planning, acetabular preparation and cup trialling. Sub-optimal component positioning may lead to edge loading, dislocation, increased wear and polyethylene fracture.

The target cup inclination (as measured on radiographs) should be 40 - 45 degrees taking into account local soft tissue and anatomic landmarks. The target cup anteversion (as measured on radiographs) should be 15 - 20 degrees taking into account soft tissue and anatomic landmarks.

An alignment guide is provided to assist with cup positioning; however, cup orientation in the patient depends on patient position. The alignment guide does not allow for variation in patient position with respect to the operating table and it should be noted that patient orientation can vary throughout the procedure.

The alignment guide system may be used to indicate an acceptable level of acetabular inclination and version. Once assembled, the inserter handle should be raised until the vertical bar is perpendicular to the plane of the operating table, with the patient in the lateral decubitus position, and the version guide parallel to the floor. (Fig.12)

The inserter handle should then be rotated until the horizontal bar is in line with the patient's longitudinal axis. (Fig.13)

The extended arm of the version guide follows the long axis of the patient's body, corresponding to the effected hip, to achieve appropriate anteversion.

Confirm complete trial seating by sighting through the holes and cutouts in the acetabular trial cup. The screw hole pattern in the trial cup replicates the implant screw hole pattern to assist with screw targeting.

Do not use trial cups to prepare screw holes. Prepare them only through the final implant.

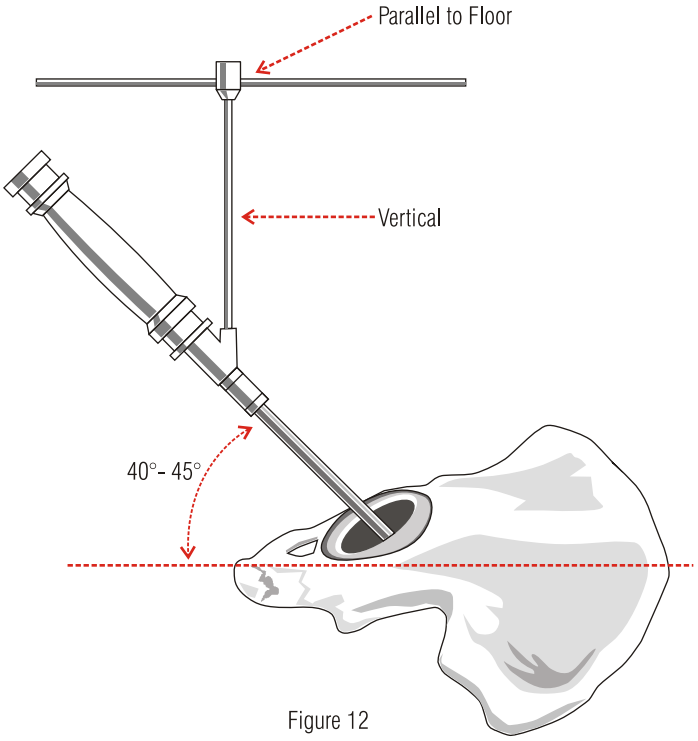


Figure 12
Hold the version guide parallel
to the floor and select the abduction angle

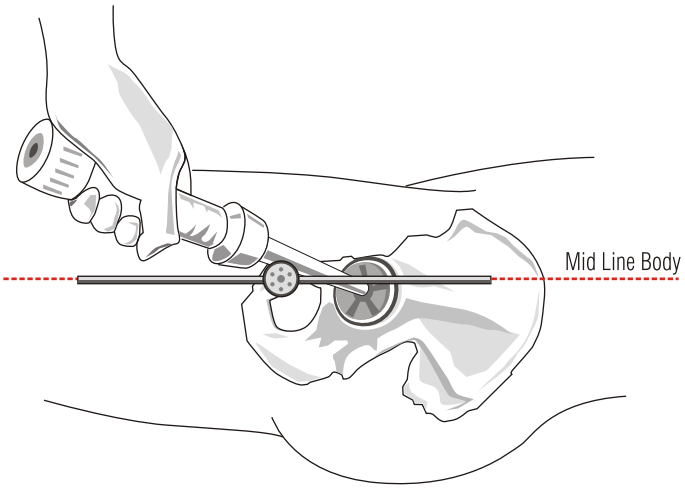


Figure 13
Position the extended arm of the version guide on the long body axis to determine anteversion (30° anteversion angle on the alignment guide relates to 20° of anteversion radiographically)

Polyethylene Trial Liner Placing

Following positioning and seating of the acetabular cup trial, place the appropriate sized liner trial into the trial cup. Secure the liner trial to the cup trial through the apical hole screw using a standard hex head screw driver.

With the femoral component trials in position, assess stability and range of motion. Couple the liner trial with cup trial in the desired position.

Femoral Canal Preparation

Ensure that broaching is started posterolaterally. The broach should run parallel to the posterior cortex following the natural anatomy of the femur. Begin with the smallest broach attached to the broach handle and increase the size of broach sequentially until longitudinal and rotational stability is achieved. Broaching should then be stopped. Careful pre-operative planning is key to help selection of the final broach size. The version will be determined by the natural version of the femur. (Fig. 14)

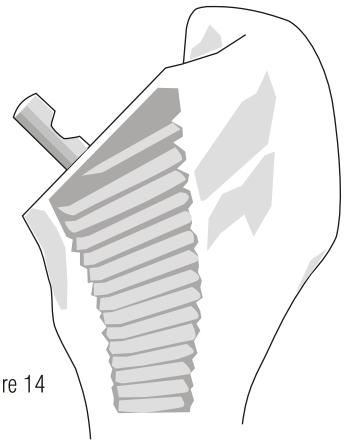


Figure 14

In Type A femurs the diaphysis should be reamed prior to broaching to ensure that the stem is implanted into compacted cancellous bone in the metaphysis

Calcar Reaming

If concern around sizing still exists, intra operative x-rays could be considered, where available. (Fig. 15)

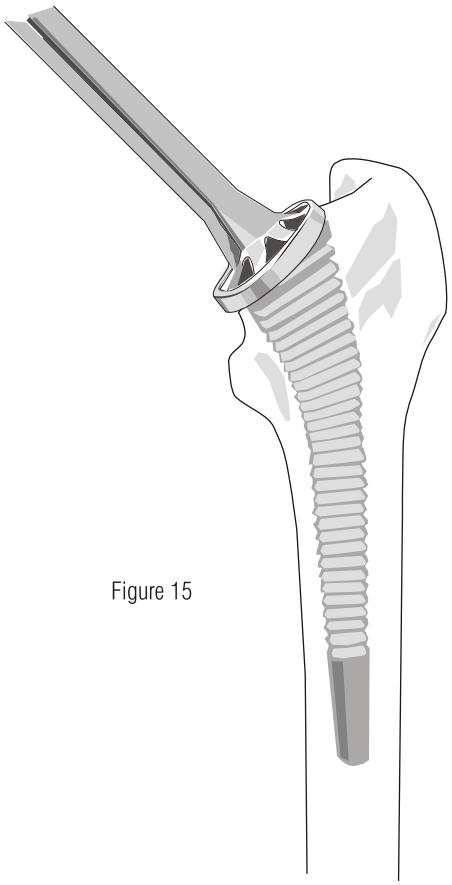


Figure 15

Trial Reduction

Leave the last broach in place and use the calcar mill to achieve a flat resection surface. The calcar reaming should allow an optimised fit of collar on the calcar. (Fig. 16)

Note: Ensure all soft tissue is clear before performing calcar reaming.

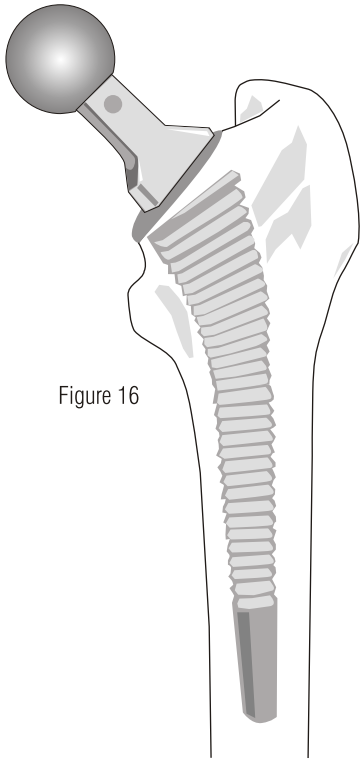


Figure 16

Implanting the Acetabular Cup With Screw Fixation

Screw Insertion

The acetabular cup has 3 screw holes and is designed for insertion with screws. Two medial hole alternatives are placed to enable screw placement up the posterior columnin either the left or right hip. The single lateral screw provides additional access to the illium.

The drill bit is controlled by the drill guide as it passes through selected holes into the acetabulum. (Fig.17) The screw angle may vary by as much as 34 degrees (Fig.18). Drill bits of varying lengths are available. By seating the drill bit completely into the guide, holes corresponding to the effective length of the drill bit will be created.

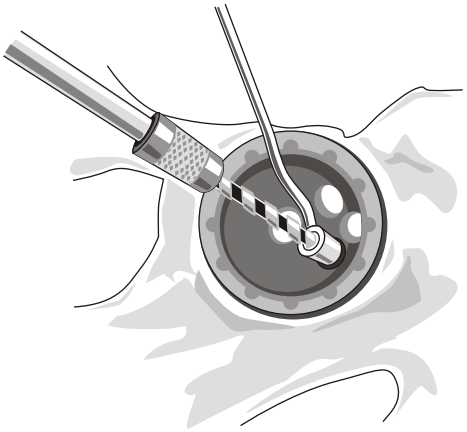


Figure 17
Drill Guide

Select holes where the prosthesis is to be anchored with cancellous screws so that screws lie within a safe quadrant. The safe quadrant is defined by two lines from the anterior-inferior iliac spine through the centre of the acetabulum and posterior by a line from the sciatic notch to the centre of the acetabulum (Fig. 19)

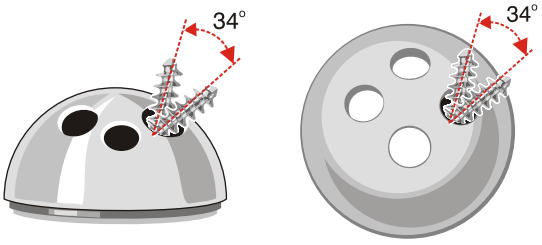


Figure 18
Screw Angulation

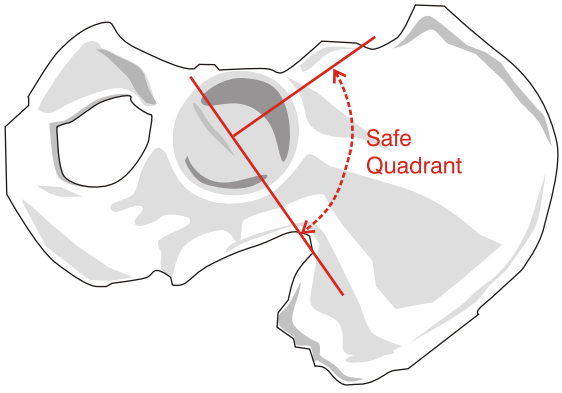


Figure 19
Screw hole selection

Verify hole depth using the Depth Gauge. Insert 6.5 mm cancellous fixation screw using a hex head screw driver (Fig. 20, 21 & 22).

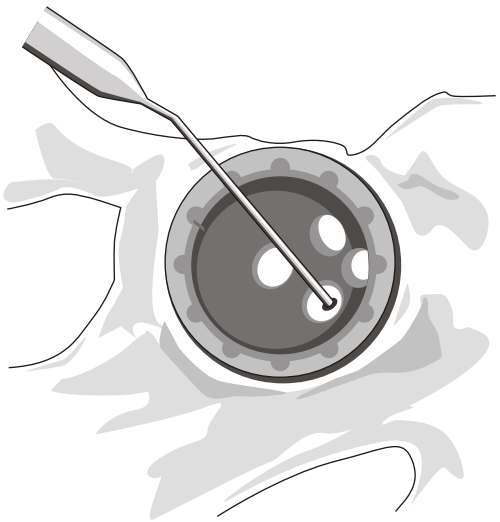


Figure 20
Depth Gauge

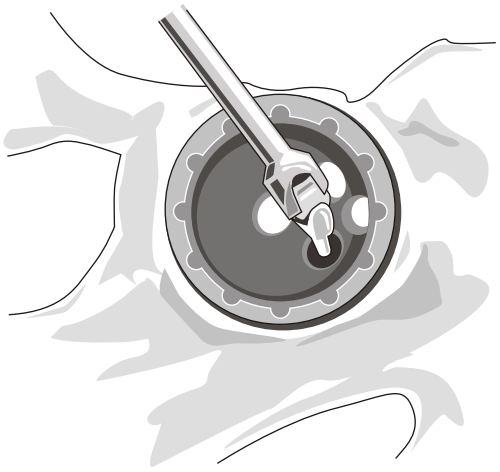


Figure 21
Screw insertion

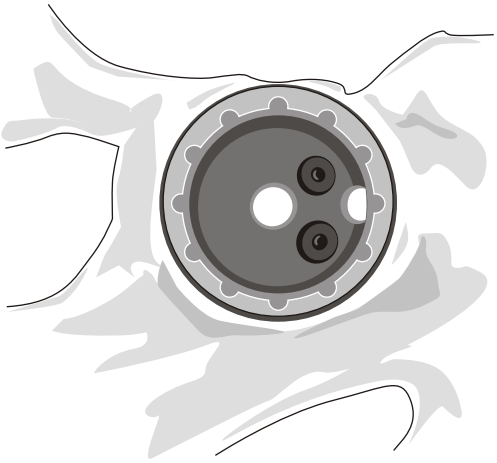


Figure 22
Screw insertion

Femoral Component Insertion

The protective covers should be left on until the components are ready to be implanted. Before implanting a femoral head, the male taper on the femoral stem should be wiped clean of any blood, bone chips or any foreign materials.

With the final broach in situ, attach the appropriate trial neck and trial head. Reduce the hip and assess what adjustments, if any, are required to ensure stability through a full range of motion. Remove the trial head, trial neck and final broach. Do not irrigate or dry the femoral canal. This will help to preserve the compacted cancellous bone quality and encourage osteointegration of the stem. (Fig. 23)

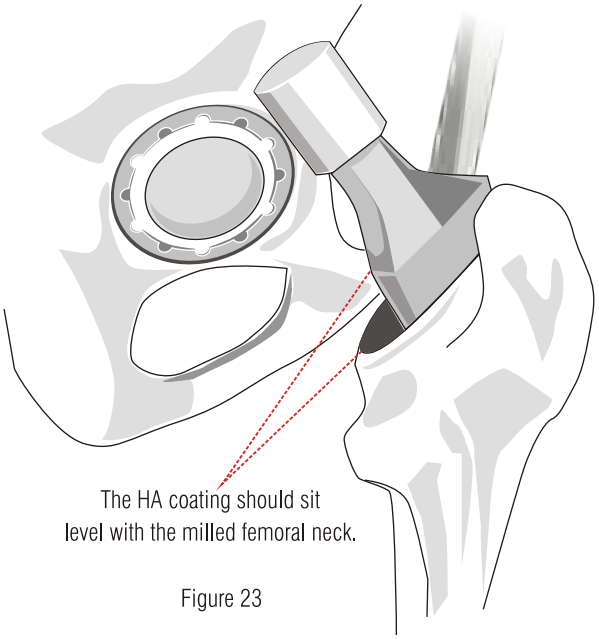


Figure 23

When implanting the definitive stem (that has the same size as final broach) in the femoral canal, ensure that it is directed in by hand. This will help avoid changing the version as a precautionary measure. You should not have more than a thumb's breadth between the resection line and the top of the HA coating on the stem. If the stem does not go down readily this far, the surgeon should broach again. (If the HA level of the stem sinks below the resection line, the surgeon should consider a larger stem). Then lightly tap the stem impactor to fully seat the stem. (Fig. 24)

Note: The stem is 0.31 mm thicker than the broach to allow the necessary press-fit.

Figure 24

Polyethylene Liner Insertion and Impaction

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

Prior to inserting the final acetabular liner, thoroughly irrigate and clean the cup. It is important to check the cup/liner locking groove to ensure it is clear of any debris. Remove all soft tissue from the face of the cup so as not to impede liner seating (Fig.25). An apex hole plug may be used prior to liner insertion.

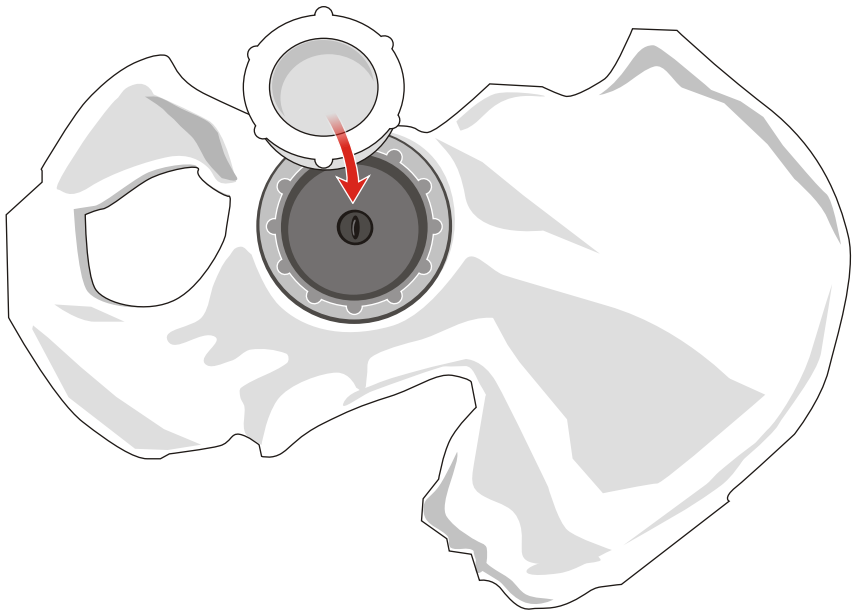


Figure 25
Liner placement

Prior to insertion/impaction, mate the liner anti-rotational device (ARD) tabs with the ARD scallops on the cup (Fig. 26). There are 6 ARD tabs on the liners and 12 ARD scallops in cup diameters 48 mm to 58 mm. Also, there are 4 ARD tabs and 8 ARD scallops in cup diameters 44 mm to 46 mm. This allows the liner to be rotated in 30 degrees increments for cups 48 mm to 58 mm and 45 degrees increments for 44 mm to 46 mm.

Seat the liner using the ID impactor that corresponds to the selected implant. Because the locking mechanism is tapered, it is important to impact the liner directly into the cup with multiple medium blows (Fig. 27).

Impacting the liner in a tilted position may prevent complete seating. Seating of the liner is visually confirmed when the liner ARDs are flush with the face of the acetabular cup; however, the liner face will remain proud in relation to the cup face by approximately 1mm (Fig. 28)

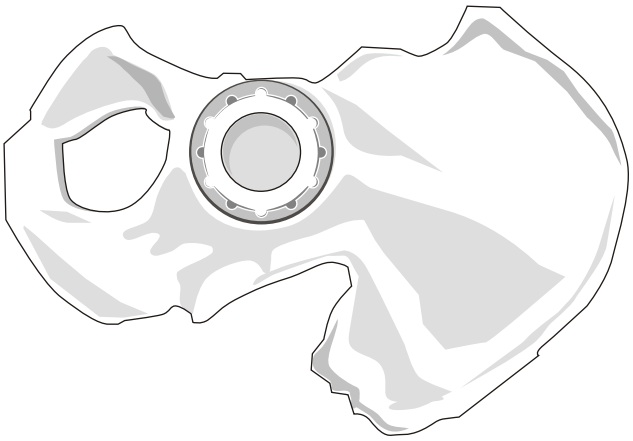


Figure 26
Align the liner anti–rotation tabs with cup scallops

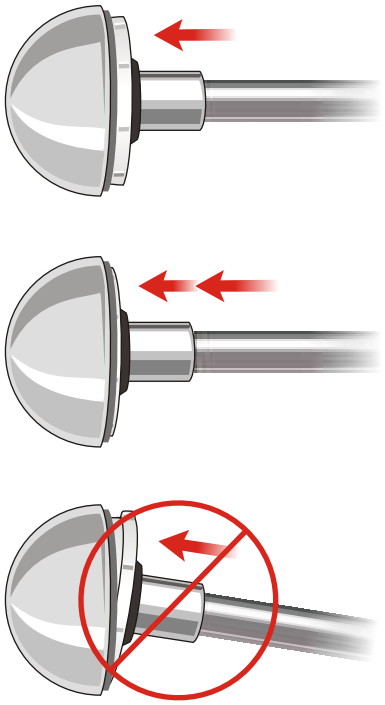


Figure 27
Liner impaction

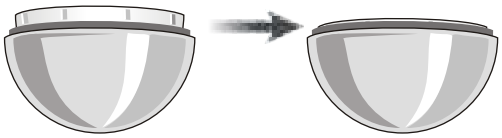


Figure 28
Seating height of a liner

Polyethylene Liner Extraction

A polyethylene liner extractor is available to aid in polyethylene liner extraction and to ensure the acetabular cup is not damaged during polyethylene liner extraction.

It is important to note that an extracted polyethelene liner must not be reused.

Femoral Head Impaction

Once the stem is fully seated, cancellous bone from the resected femoral head is added around the proximal part of the stem using the bone tamp to seal the femoral canal and to reduce the time for osteointegration which provides definitive stability.

A final trial reduction is carried out to confirm joint stability and range of motion.

Clean and dry the stem taper carefully to remove any particulate debris. Place the femoral head onto the taper and lightly tap it using the head impactor. Ensure bearing surfaces are clean and finally reduce the hip. (Fig. 29)

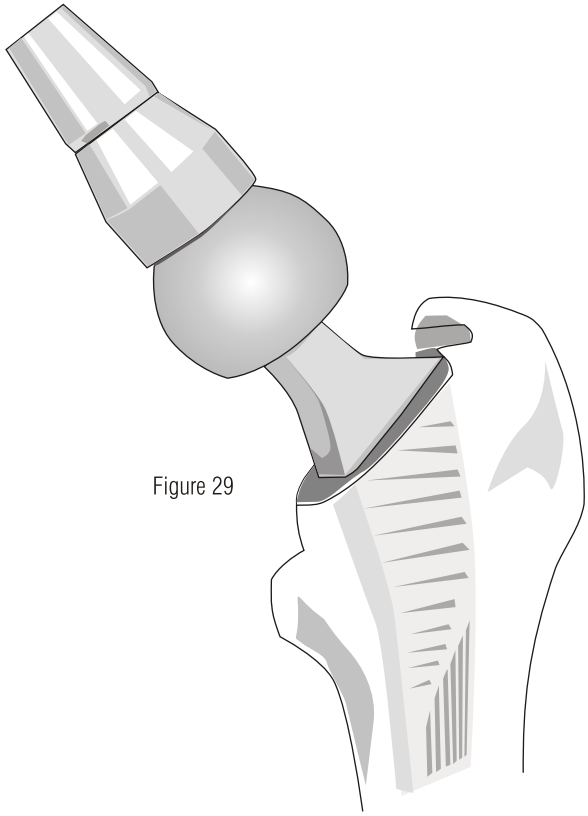


Figure 29

Functional Assessment

Correct component placement is critical for the longevity of the hip 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. (Fig. 30)

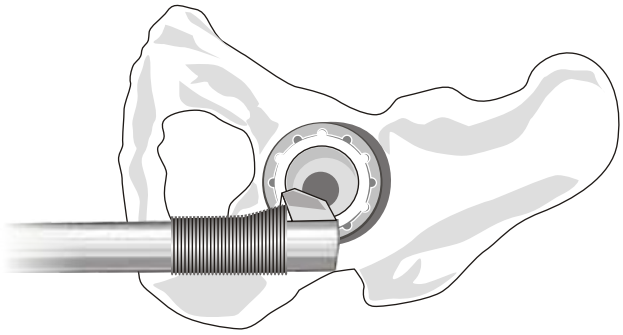


Figure 30

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 (Fig. 31) until the circumference of the femoral head becomes coplanar with the opening of the acetabular insert (ie., the axis of the femoral neck is perpendicular to the insert face). This position is depicted through a frontal view (Fig. 32) and through a lateral view (Fig. 33).

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.

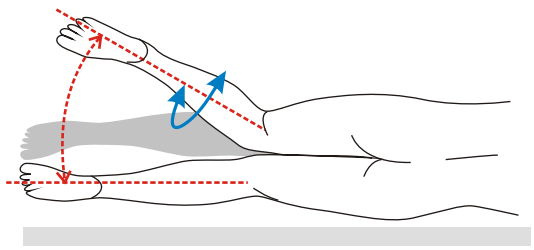


Figure 31
Combined Anteversion

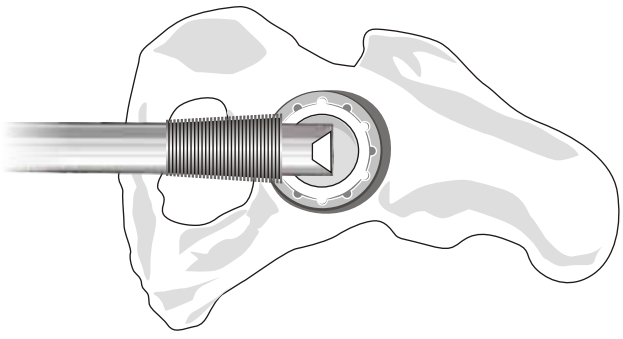


Figure 32

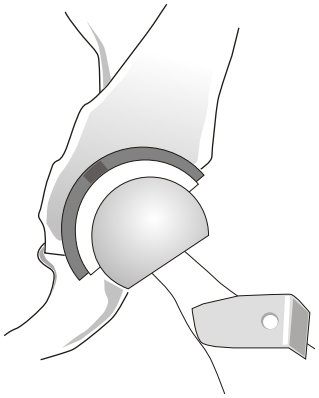


Figure 33

Tight Exposure and Stability Tips

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 formis.

Stability Assessment

Posterior Instability

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

Prosthetic Impingement

Problem

- Femoral implant neck levers on the component rim

Solution

- Reposition cup to correct version/abduction
- Increase head size and evaluate
- Increase anteversion of the stem

Bony Impingement

Problem

- Prosthetic neck levers on anterior acetabular osteophyte
- Greater trochanter impinging on ilium

Solution

- Remove anterior osteophytes from the acetabulum
- Increase stem offset to move the trochanter away from the ilium
- Remove anterior trochanteric bone

Soft Tissue Impingement

Problem

- Redundant anterior capsule causes head to lever out of socket

Solution

- Resect redundant anterior capsule

Soft Tissue Laxity

Problem

- Lax soft tissue leading to multidirectional instability

Solution

- Increase the neck length
- Advance the trochanter

Anterior Instability

With the trial implants in place, place the hip in extension and maximally externally rotate; subluxation should not occur. If subluxation occurs, determine the cause of instability.

Prosthetic Impingement

Problem

- Prosthetic neck impinges on the acetabular cup

Solution

- 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

Solution

- Increase femoral offset
- Decrease acetabular or stem anteversion

Keys to managing instability

1. Ensure appropriate anteversion/abduction of the acetabular and femoral component.
2. Restore correct leg length and femoral offset
3. Repair the posterior capsule and rotators
4. Work with the patient to ensure appropriate post-operative 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.

Atleast 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.

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