HEALTHCARE

ALTIUS™

Cemented Hip Implant System

PRODUCT MANUAL

Hip Femoral Stem (Polished & Double Tapered)

- Made of High Nitrogen stainless steel as per ISO 5832 Part 9 and ASTM F 1586.
- High strength, Corrosion resistant and Bio-compatible
- Neck Stem angle of 125^0.

Sl.No.	Ref.No.	Size	Type	Offset (mm)	M/L Dimension (mm)	Stem Length (mm)	Neck Length (mm)
1	AHFS3600	-	Small	36.0	11.0	127	46.0
2	AHFS3801	1	Narrow	38.0	13.5	149	48.0
3	AHFS3802	2	Narrow	38.0	16.0	149	48.0
4	AHFS3803	3	Narrow	38.0	18.0	149	48.0
5	AHFS4452	2	Standard	44.5	16.0	149	57.0

Hip Femoral Head

- Made of High Nitrogen stainless steel as per ISO 5832 Part 9 and ASTM F 1586.
- High strength, corrosion resistant and Bio-compatible

Sl.No.	Ref. No.	Diameter (mm)	Neck Length (mm)
1	AHFH22SO	22	Standard
2	AHFH22P4	22	+4.0mm
3	AHFH22P8	22	+8.0mm
4	AHFH28N4	28	-4.0mm
5	AHFH28SO	28	Standard
6	AHFH28P4	28	+4.0mm
7	AHFH28P8	28	+8.0mm

Hip All Poly Acetabular Cup-LPW

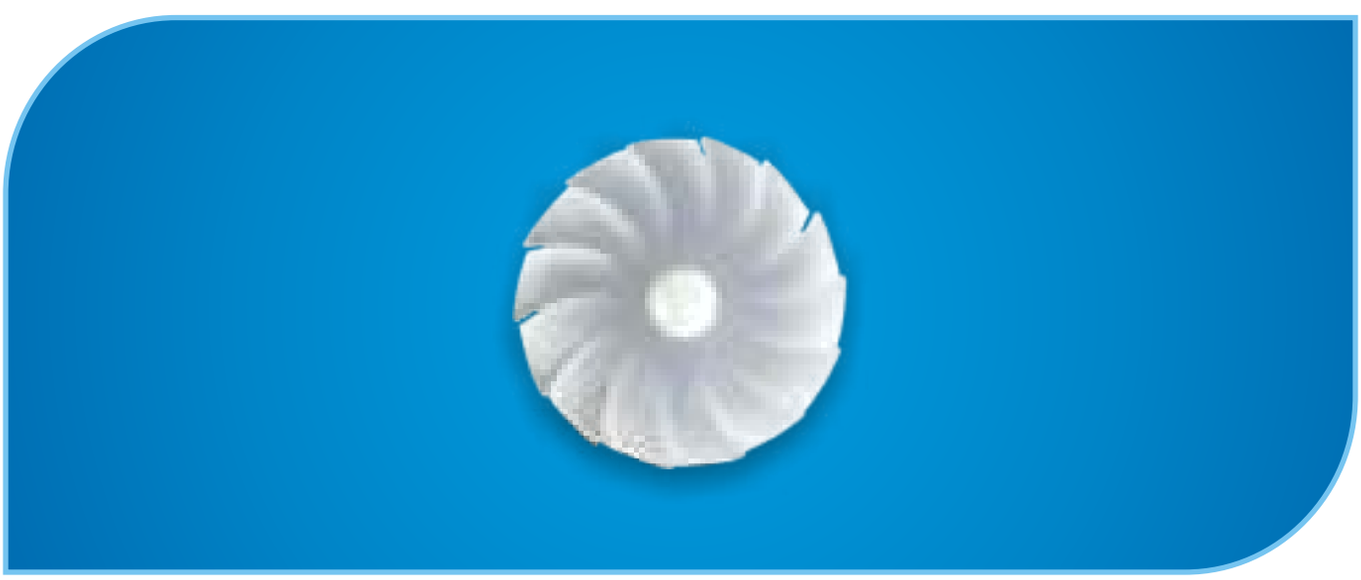
- Made of Highly Cross-linked Polyethylene (XLPE)

Sl.No.	Ref. No.	Outer Diameter (mm)	Inner Diameter (mm)
1	AHAPAC40	40	22
2	AHAPAC42	42	22
3	AHAPAC44	44	28
4	AHAPAC46	46	28
5	AHAPAC48	48	28
6	AHAPAC50	50	28
7	AHAPAC52	52	28
8	AHAPAC54	54	28
9	AHAPAC56	56	28
10	AHAPAC58	58	28

Centralizer

- Made of PMMA (Polymethyl methacrylate).
- Provides a minimum of 3mm clearance at the bottom of the Stem.
- The centralizer is designed to allow stem to engage distally within the cement mantle.

Cement Restrictor



- Made of UHMWPE.
- This is connected to the end of the Stem and is used to control the Cement flow.

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DESIGN RATIONALE

Anatomic Reconstruction

- The objectives of total hip replacement are to:
  - relieve pain
  - increase mobility and function

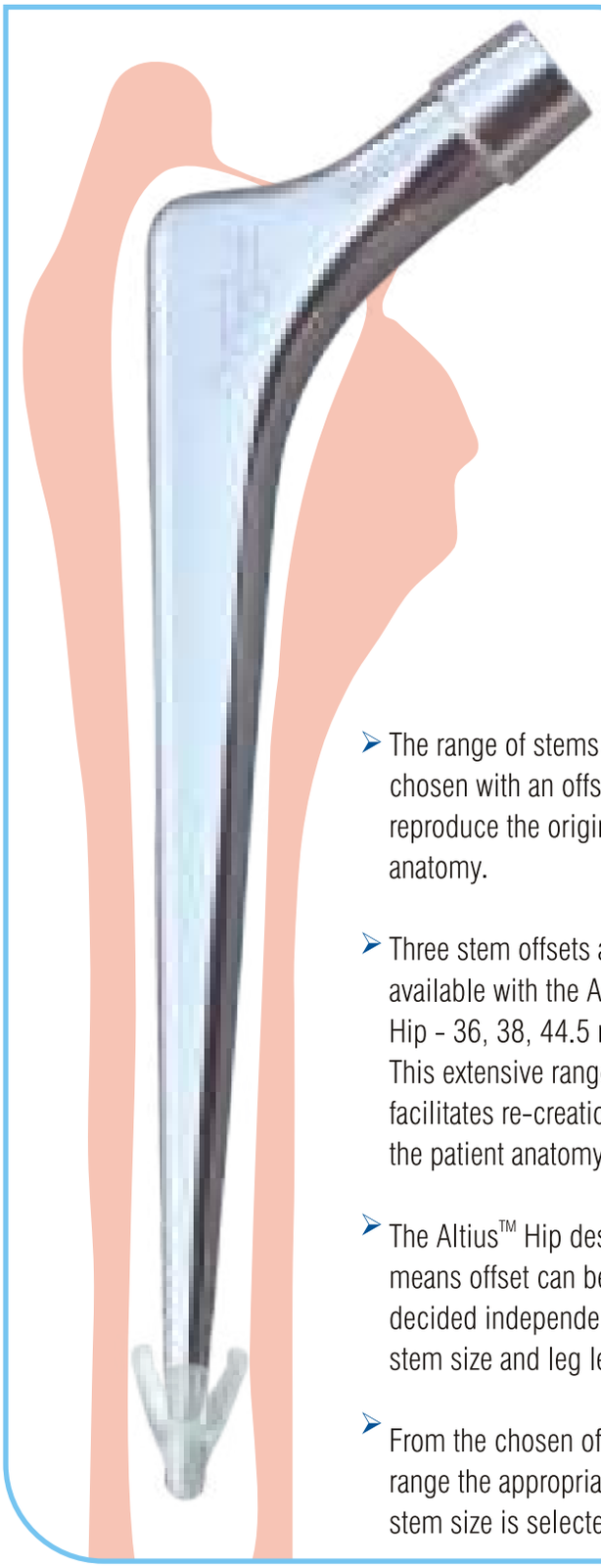
- Achieving a correct anatomic reconstruction maximises these objectives.

- The unique design of the Altius™ Hip greatly assists the correct restoration of the patient's original anatomy through the ability to alter intra operativley:
  - Leg length
  - Offset
  - Stem version

  Each of these variables is independent of the others.

- In order to minimise the risk of dislocation, different head size diameters may be used. Increasing the head size increases the range of motion arc and jump distance, reducing impingement and decreasing the risk of dislocation. Total hips with larger diameter heads are more resistant to dislocation.

Offset



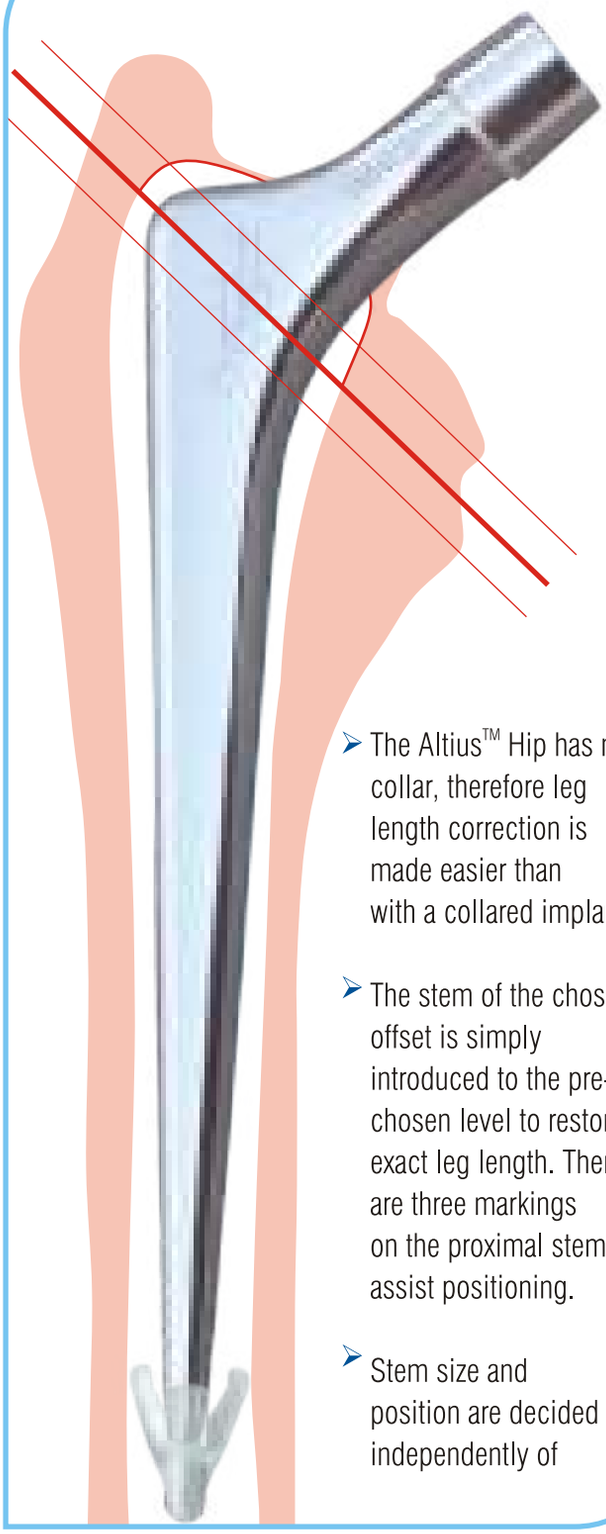
- The range of stems is chosen with an offset to reproduce the original anatomy.

- Three stem offsets are available with the Altius™ Hip - 36, 38, 44.5 mm. This extensive range facilitates re-creation of the patient anatomy.

- The Altius™ Hip design means offset can be decided independently of stem size and leg length.

- From the chosen offset range the appropriate stem size is selected.

Leg Length

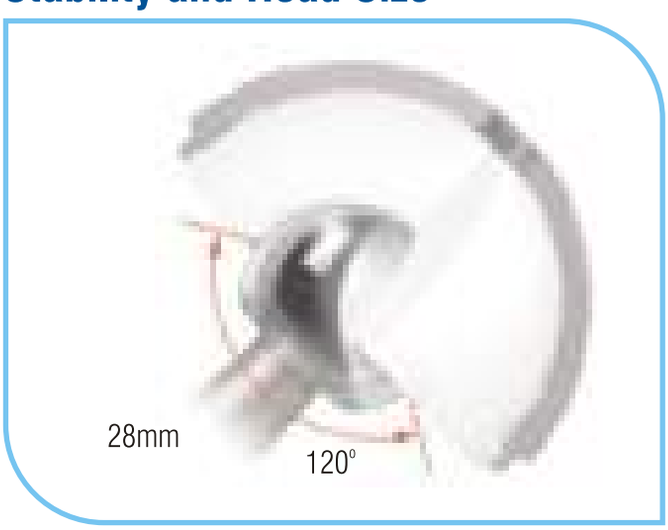


- The Altius™ Hip has no collar, therefore leg length correction is made easier than with a collared implant.
- The stem of the chosen offset is simply introduced to the pre-chosen level to restore exact leg length. There are three markings on the proximal stem to assist positioning.
- Stem size and position are decided independently of

Stem Version

- The Altius™ Hip may be implanted in natural anteversion (15 degrees) or in additional anteversion or retroversion if clinically indicated.
- As it is a cemented implant, the stem version can be changed intraoperatively during femoral preparation and/or final implantation.

Stability and Head Size



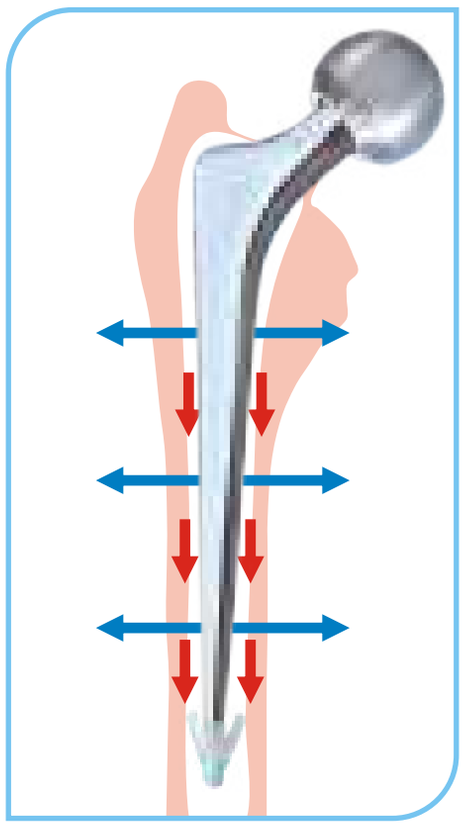
- Head sizes up to 28 mm in diameter are available for use with Altius™ and may assist in reducing the rate of dislocation due to an increased range of motion and jump distance.

- The polished double tapered Altius™ stem creates radial compressive loading as the predominant force, unlike a non-polished surface non tapered stem, which creates greater shear force as stem migrates distally.

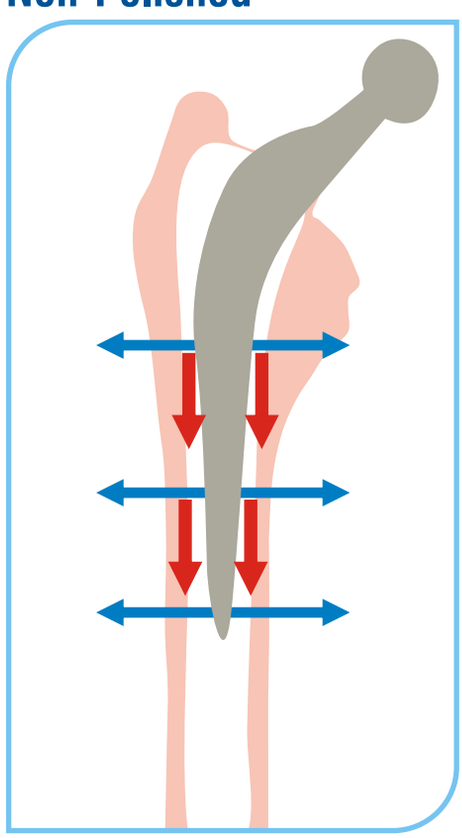
- Distal stem migrates at the cement-implant interface with the polished Altius™ stem. The nonpolished design migrates not only at the cement-implant interface, but also at the cement-bone interface. Migration at the cement-bone interface may interfere with fixation.

- There are significant differences in rapid posterior head migration of the polished Altius™ compared to that of a non-polished design. The subsidence of the polished, collarless, tapered stem within the cement mantle compresses the interfaces and renders them more able to resist shear forces generated by the posteriorly directed loads on the femoral head. Polished, collarless, tapered stems are more forgiving than conventional designs.

Polished



Non-Polished



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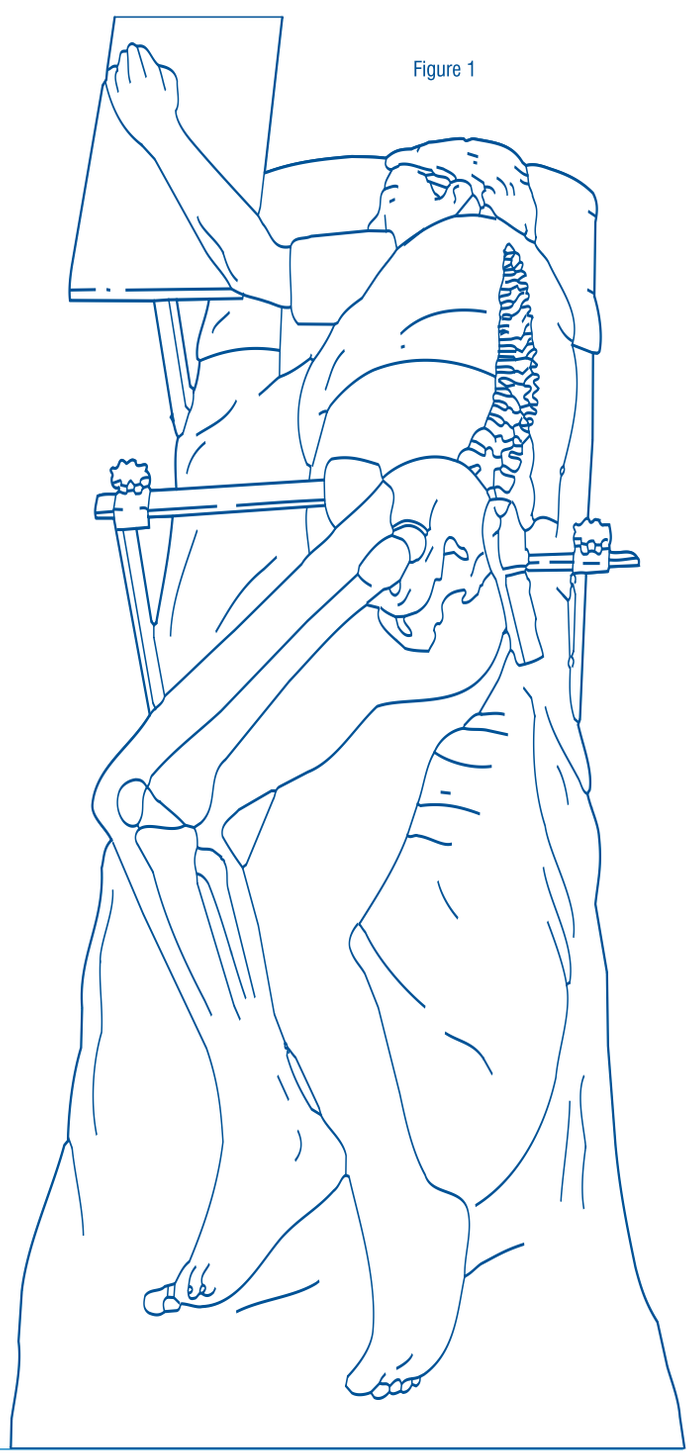
SURGICAL PROCEDURE

1. Pre-operative Plannings

- Pre-operative templating is important and will usually allow the surgeon to select an implant of the appropriate size and offset for the hip to be reconstructed, and to plan the positions in which the components should be placed (Fig. 1).

  Allowance must be made for the need to obtain a complete mantle of cement for the femoral component that is to be used. Alongside the stem profiles on the templates are marks that demonstrate the extent of cement mantles of varying widths. The first mark indicates the minimum mantle allowed. It may be necessary to template the opposite hip.

Figure 1



2. Surgical Exposure

- The Altius™ Hip can be implanted through the anterior approaches or through posterior approach. The posterior approach is featured in this technique manual. Whichever approach is used, a full exposure of both the acetabulum and the proximal femur is essential for effective preparation of the bony cavities, cementing, and implant insertion.

  Appropriate soft tissue releases shall be performed to allow adequate exposure of the whole socket rim and mobilisation of the proximal femur.

  The patient must be firmly and accurately supported in the lateral decubitus position (Fig.1) to help ensure that the acetabular component is orientated correctly. It is also important not to flex the contralateral hip too much as this could reduce the lumbar lordosis, with subsequent risk of retroversion of the cup.

  Either the femur or the acetabulum may be prepared first.

3. Femoral Neck Resection

- The level and orientation of neck resection is not critical as the Altius™ Hip Stem has no collar or other features which will affect the osteotomy line. The level of section usually runs from mid-way between the upper margin of the lesser trochanter and the inferior aspect of the head, to the upper surface of the base of the neck (Fig. 2).

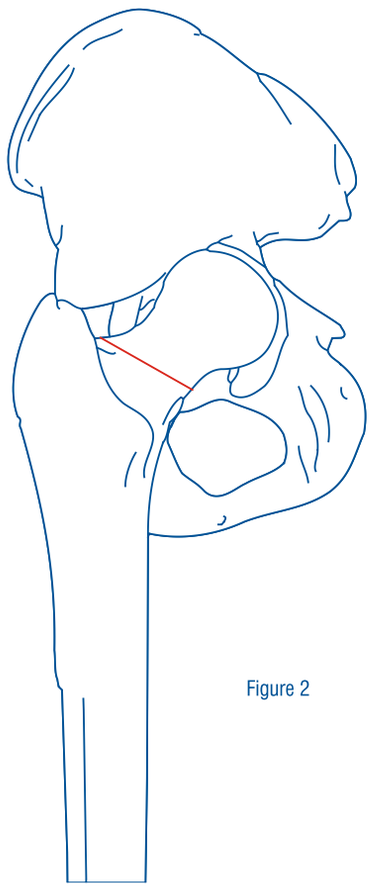


Figure 2

4. Acetabular Preparation

- The true acetabular lip is identified, osteophytes are removed with any redundant capsular folds, and the transverse acetabular ligament is left intact. The true floor of the socket is identified.

  Grater reamers are used to remove all remnants of articular cartilage and to shape the cavity with exposure of a cancellous surface where feasible, except on the medial wall. The curtain osteophyte is then removed. The cortical layer above the teardrop is never removed. The reamer shaft should be orientated at 40° of abduction and 10°-15° of anteversion (Fig. 3).

  Care must be taken not to enlarge the antero-posterior diameter of the acetabulum, unduly thinning the anterior and posterior walls.

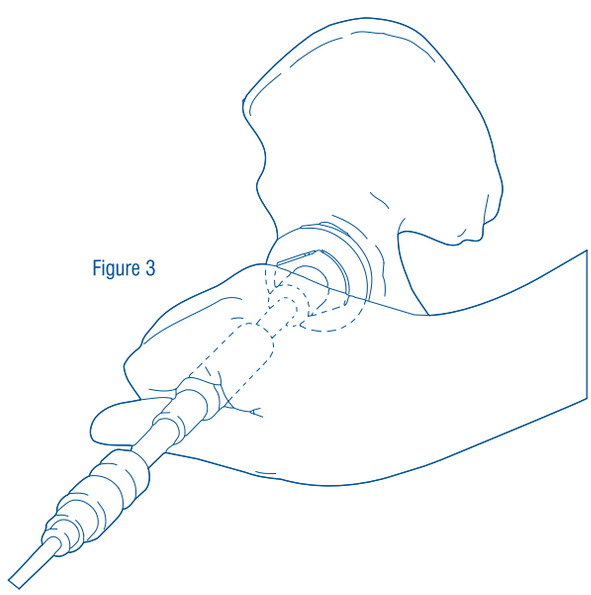


Figure 3

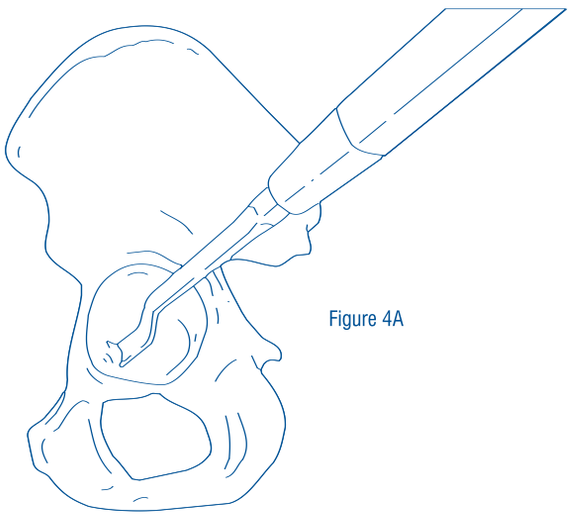


Figure 4A

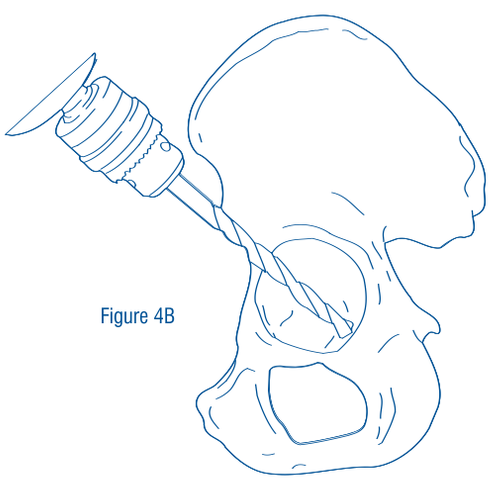


Figure 4B

A gouge may optionally be used to create fixation pits in the three main bones of the pelvis (Fig. 4A). Multiple drill holes are then made in the ilium, pubis and ischium for fixation (Fig. 4B).

Supplementary 6mm drill holes should also be used where appropriate, especially just within the rim of the acetabulum. Trial cups are inserted into the prepared acetabulum to confirm or change the selection of cup made on the basis of preoperative templating. The selected trial cup must be completely surrounded by bone (Fig. 5A).

The pressuriser is tested against the acetabular rim to make certain that a perfect seal is obtained (Fig. 5B). Cancellous autograft chips taken during the preparation of the upper femur or during the preparation of the acetabular pits should be packed under the transverse ligament to ensure that the space underneath is totally occluded. Any other rim deficiencies should be made good with impacted cancellous chips, and it is usual to place a layer of cancellous bone chips on the cortical floor of the acetabulum just above the teardrop. These are held in place with the outer side of a long spoon whilst the acetabulum is cleaned.

5. Acetabular Cementing and Pressurisation

- The acetabulum is thoroughly cleaned using lavage. It is irrigated with Hartmann's solution, and packed with swabs soaked in 10 vols. hydrogen peroxide whilst the bone cement is being mixed. These swabs are held firmly in place using the cup pusher until the cement is ready to use.

  A sucker-aspirator may be used to assist cement intrusion and prevent blood accumulating at the interface. The cement mass is placed into the socket, and cement is thumbed into the pits. The level of cement in the acetabulum should be approximately 5mm below the acetabular rim to ensure a good seal by the pressuriser (Fig. 5C).

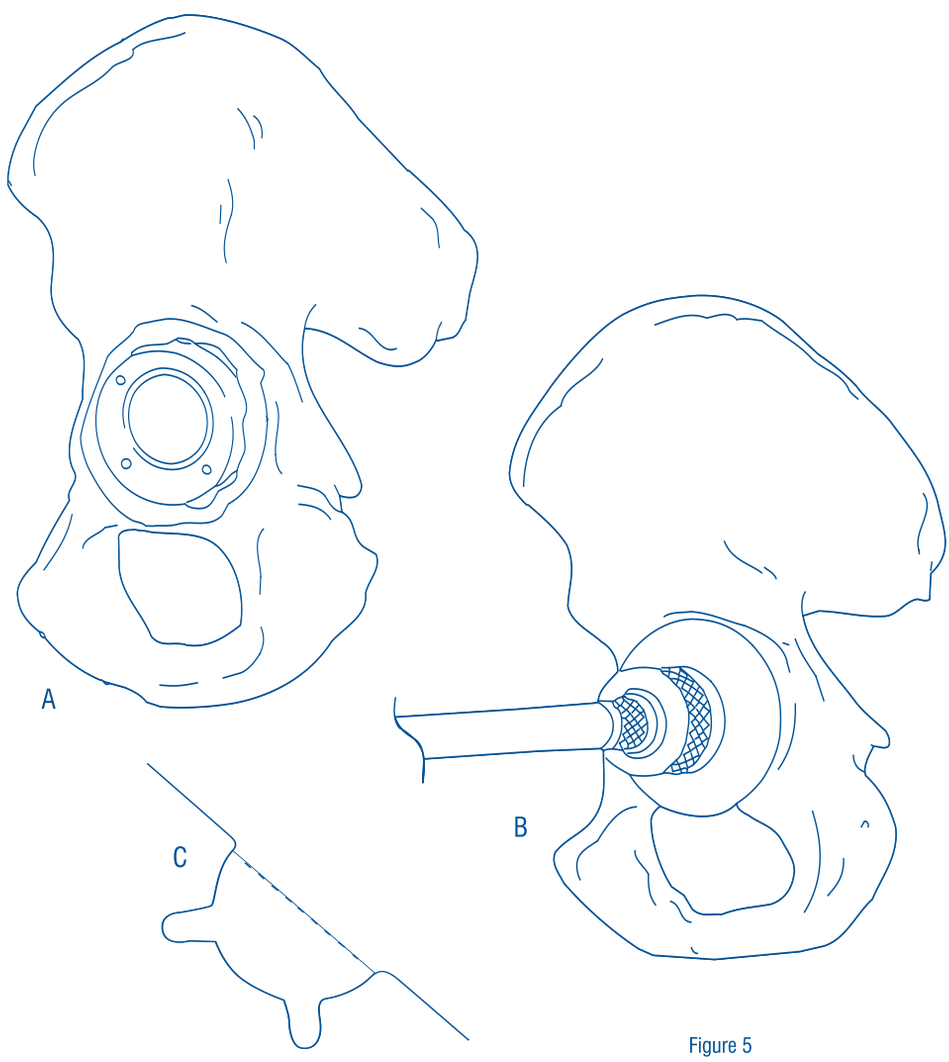


Figure 5

- The cement is pressurised using the acetabular pressuriser. A piece of gauze and a latex sheet are placed over the pressuriser balloon. The balloon is inflated, then applied to the socket rim and then pushed with considerable force.

  Pressurisation should continue until the viscosity of the cement has risen sufficiently to overcome the bleeding pressure of the bone.

  A quantity of cement should be held in the surgeon's hands to help ascertain when cement reaches the stage when the cup should be implanted. Normally this stage will be reached at 6-8 minutes after commencement of mixing.

  The pressuriser is removed by deflating the balloon, then breaking the seal by lifting the gauze swab and peeling back the latex sheet.

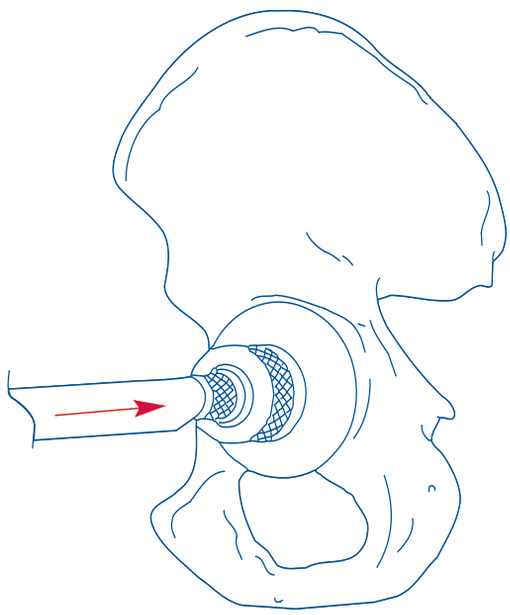


Figure 6

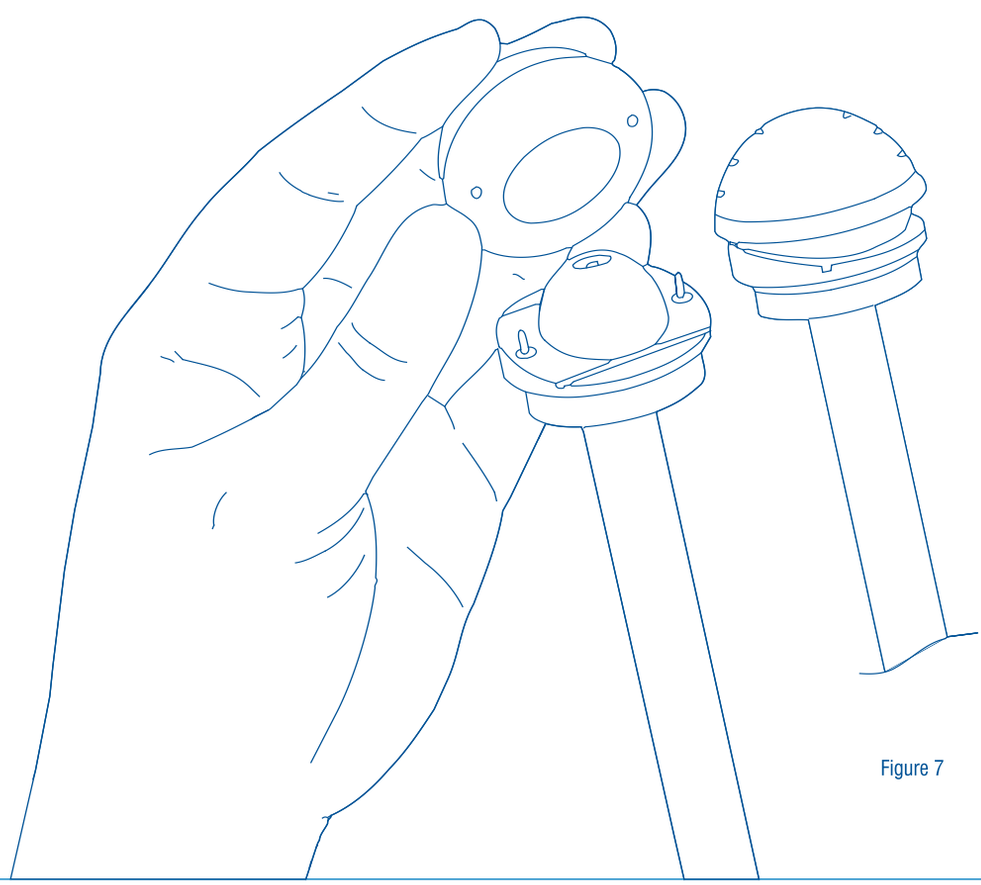


Figure 7

6. Acetabular Implantation

- The acetabular cup is then implanted. It is positioned onto the introducer (Fig. 7), and pushed into the acetabulum. Considerable force should be necessary to overcome the viscosity of the cement, but the cup should not be allowed to bottom out. The initial force applied is medial and then superiorly.

  The cup is correctly positioned when the face of the cup is at an angle of 40° of abduction and 10°-15° of anteversion (Fig. 8). The guide rods on the introducer will place the cup in this orientation if they are correctly used and provided the patient has been accurately placed and stabilised in the lateral decubitus position (as detailed previously in Fig. 2). If the direct lateral or lateral approach has been used the cup may be placed in a more neutral position. During insertion the cup should be rotated so that the apex of the skirt should lie posterolaterally either at 10 o'clock or 2 o'clock according to the side. The long alignment rod should be vertical, and the short pin horizontal and at 90º to the patient's long axis. There should be an adequate thickness of cement between the cranial surface of the cup and the acetabular bone of no less than 3 - 4mm. This layer will of course be appreciably thicker in the region of the fixation pits.

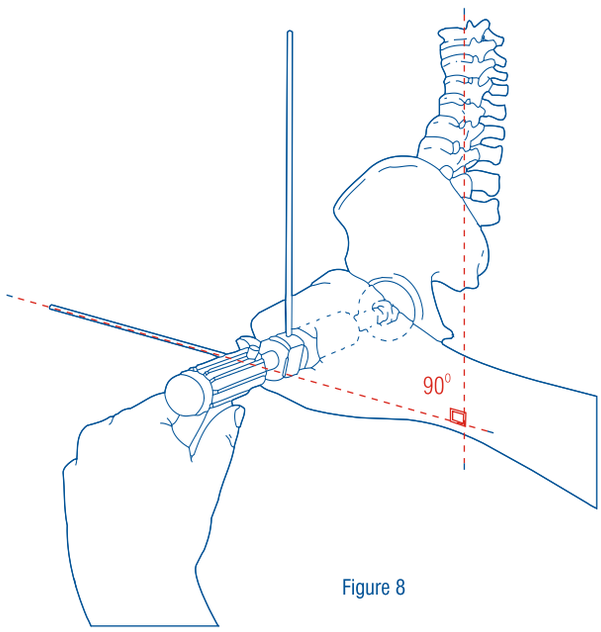
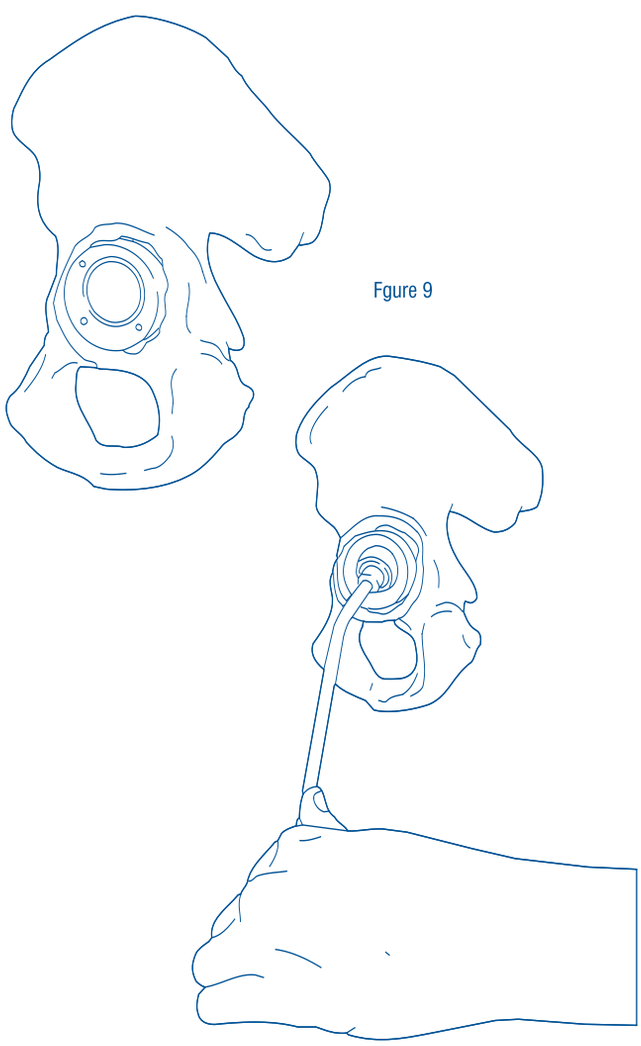


Figure 8



Fgure 9

Once the cup has been properly positioned, it is held in place with light pressure using the universal cup pusher, with the appropriately sized trial femoral head, so that there is no tendency for the cup to be moved within the cement mantle whilst the cement is polymerising (Fig. 9).Avoid using a damaged trial head which may lock in the cup and cause it to move. After cement polymerisation the fixation is checked by rocking the cup and watching for evidence of 'pumping' of blood at the cement-bone junction. Evidence of this indicates inadequate fixation, and immediate revision should be considered.

Significant osteophytes should be removed to prevent premature impingement of the femoral component or femur on the acetabular rim at the extremes of movement. If during trial reduction the neck of the prosthesis impinges on the skirt then that part of the skirt should be resected.

7. Femoral Preparation

➢ The leg is positioned and held with a femoral elevator. A gluteus medius retractor may be used to fully expose the proximal femur (Fig. 10).

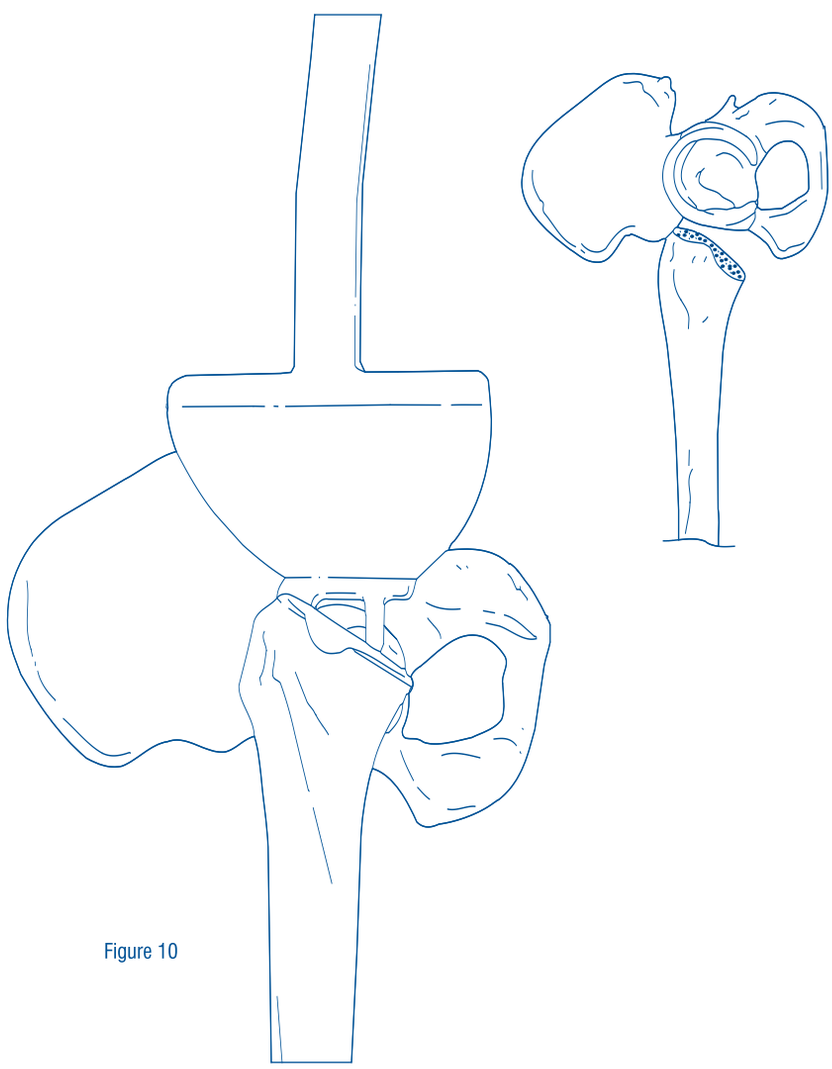


Figure 10

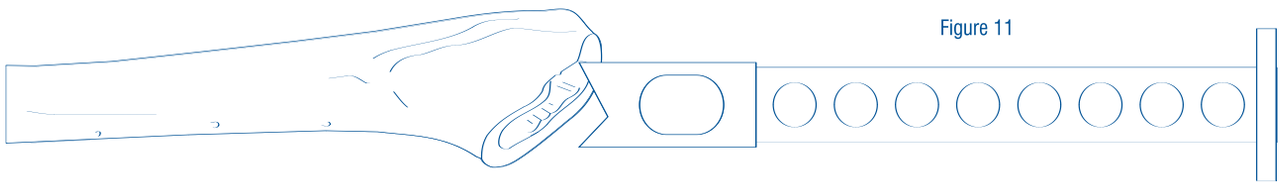


Figure 11

- The opening in the cut surface of the femoral neck is developed from within the calcar toward the proximal aspect of the greater trochanter as far as necessary to allow the Altius ™ stem to be passed directly down the femur in the long axis of the medullary canal.

  The cavity is opened using the straight Capener type gouge or a box chisel, to undercut the base of the neck, and develop the slot into the trochanteric region (Fig. 11), if necessary using a rongeur to resect the bone of the neck after undercutting. The taper pin reamer is used to develop the slot to ensure that the femoral stem can be inserted down the mid-line of the femur.

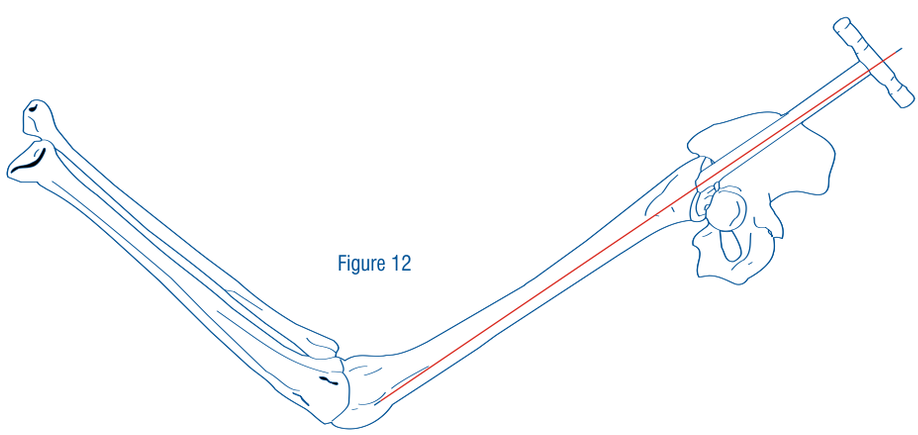


Figure 12

- The taper pin reamer should be positioned within the canal so that it aligns with the popliteal space (Fig. 12), or with the patella if the lateral approach is being used.

  Trabecular bone is removed from within the calcar until a strong layer is encountered, usually this will leave 2 - 3 mm of strong trabecular bone.

  This layer of trabecular bone provides a firm foundation for the micro-interlock of cement within the bone.

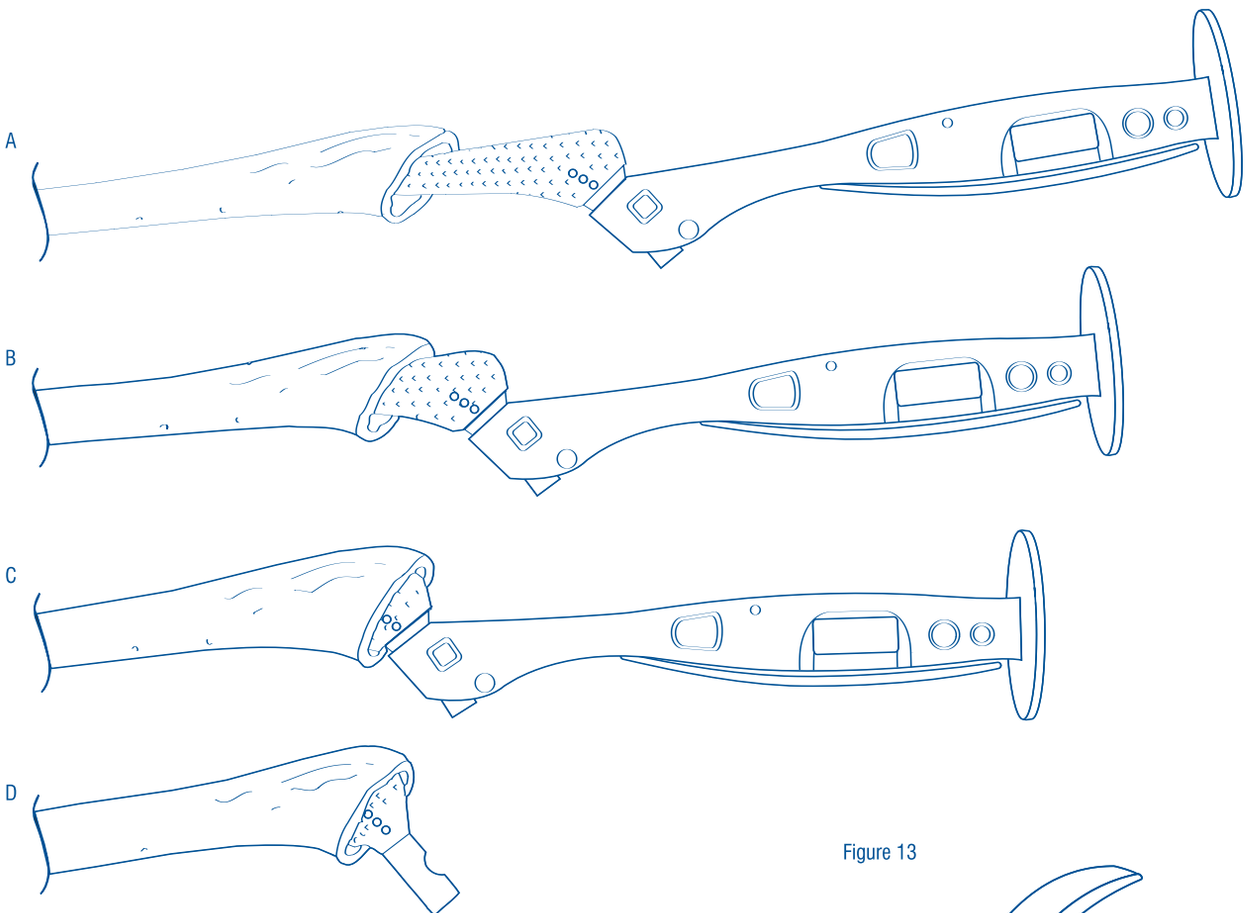
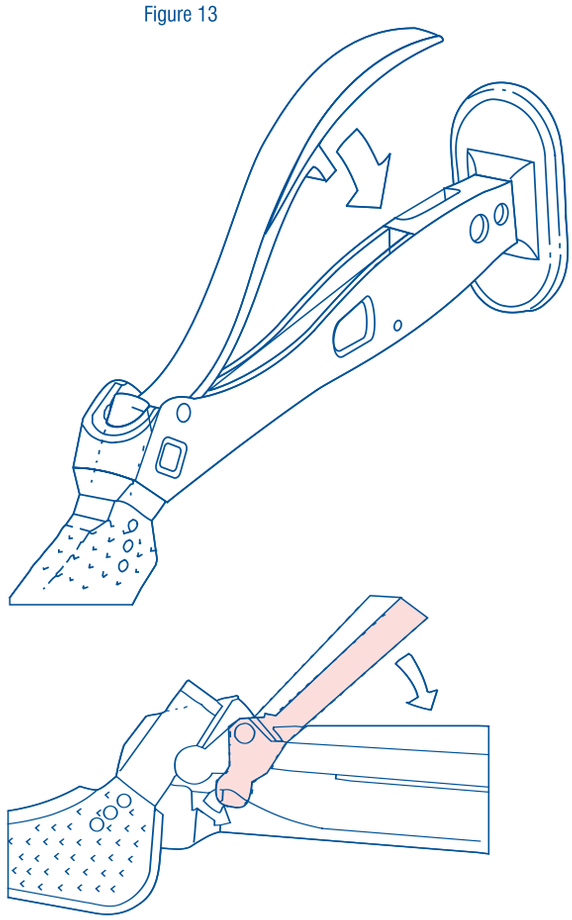


Figure 13



- A smaller rasp is used initially finishing with the rasp corresponding to the template considered appropriate for the femur. It is a serious mistake to over-rasp the canal and remove too much cancellous bone.

  If excess force is required to introduce a rasp to this level then the canal should be further developed with the taper pin reamer or gouge, without compromising the layer of strong trabecular bone.

8. Trial reduction

- The proximal femur is re-exposed and the appropriate head trial is positioned onto the rasp. A trial femoral head is placed over the spigot and the hip is reduced. Head trials are colour coded; blue is for a minus (-) neck length, black for neutral and green for a plus (+) neck length.

  Correct restoration of leg length may be assessed by comparing the relative positions of the femoral condyles. If the leg has been shortened this can be compensated for by implanting the stem to a higher level. Leg lengthening can be compensated by impacting the rasp further into the femur and repeating the trial reduction. A smaller rasp may be required.

  When the correct leg length has been achieved, the trial femoral head is removed and a metal spigot protector is positioned over the neck trial. The stem introducer is mounted onto the metal spigot protector ensuring that it is aligned with the rasp. The femur can be marked with diathermy and methylene blue dye at the level indicated by the leg length gauge (Fig. 14). Alternatively a K wire may be used. The spigot protector and neck trials are then removed. The rasp handle is reattached and the rasp removed.

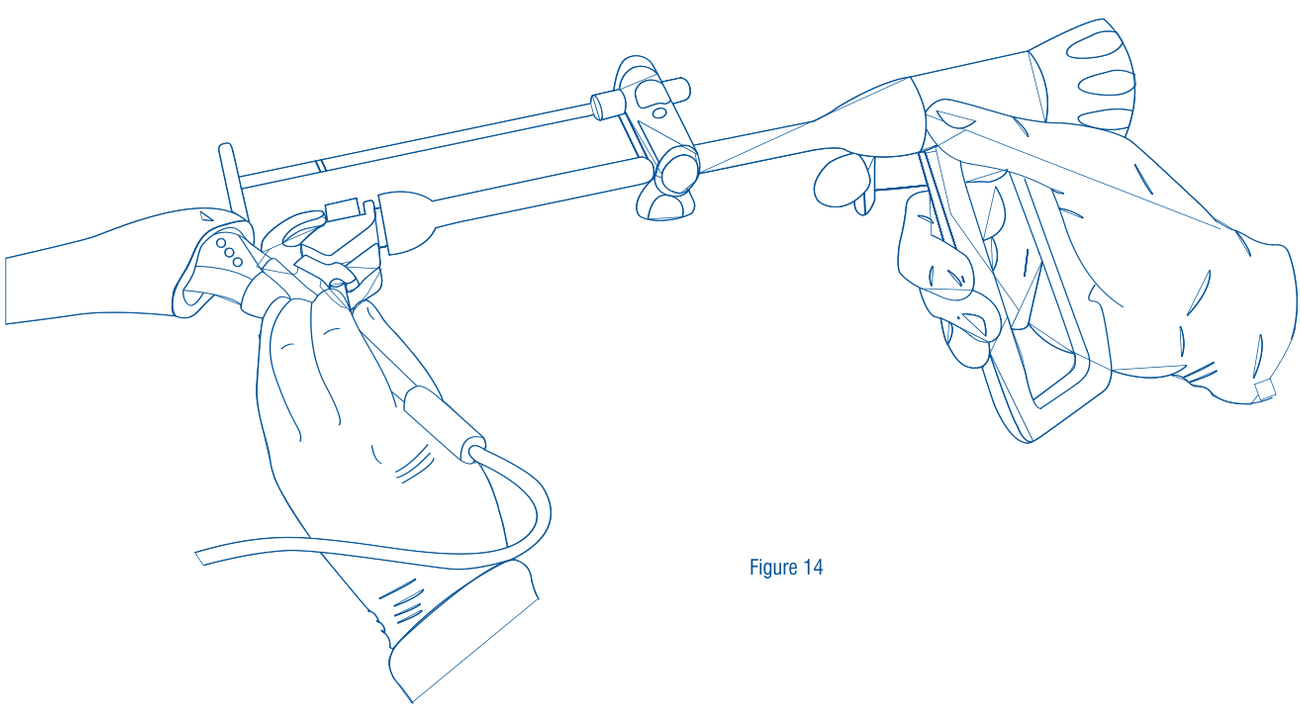


Figure 14

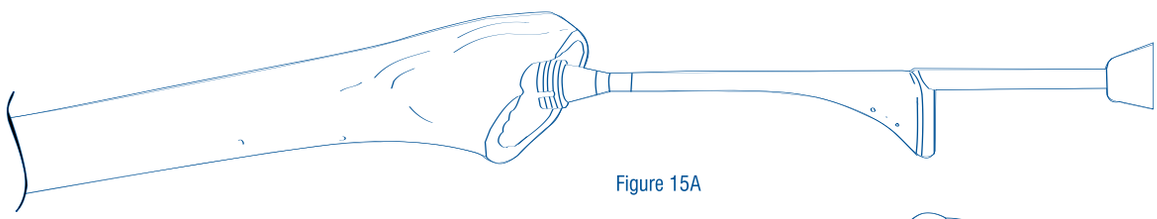


Figure 15A

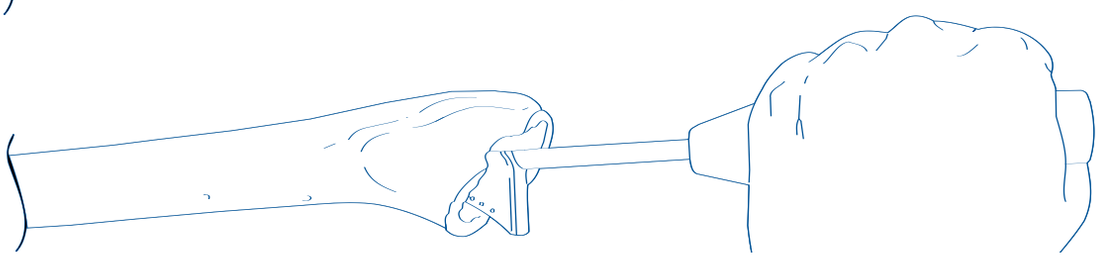


Figure 15B

9. Further Femoral Preparation

- The correct intramedullary plug size is selected by using Altius™ plug trials. The appropriate size of intramedullary plug is mounted on the introducer (Fig. 15A), and driven in 17 - 18 cm distal to the tip of the greater trochanter (Fig. 15B).

  A tight fit for the plug is essential.

  The proximal femoral seal and backing plate are positioned onto the cement gun nozzle. These are placed over the proximal end of the femur to ensure a good fit (Fig. 16). If a good fit cannot be achieved, the other size of seal should be tried, or the femoral slot altered to ensure a tight seal. If a tight fit cannot be obtained after any of these measures, the use of the gun should be abandoned and the 'suck-down' technique should be used with doughy cement and vigorous finger packing. The canal is thoroughly cleaned using lavage. A catheter is placed in the distal end of the canal and connected to suction.

  Ribbon gauze soaked in 10 vols. hydrogen peroxide is packed into the femur to maintain haemostasis in the canal and to provide a clean dry surface into which the cement can key. The ribbon gauze and suction catheter are removed immediately before cement injection starts.

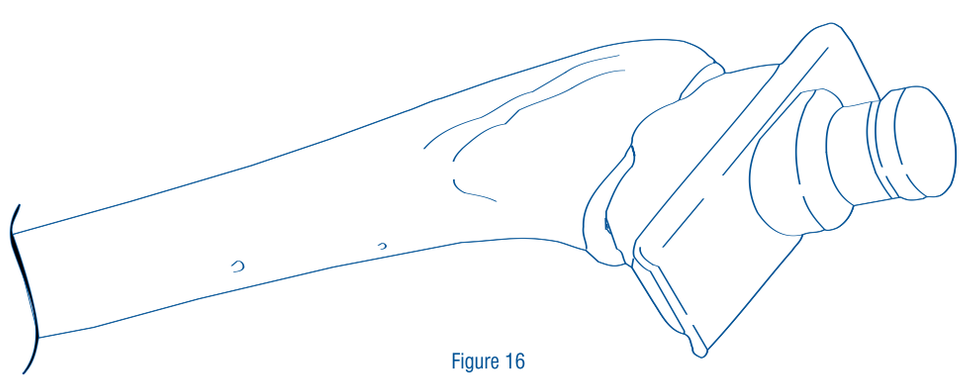


Figure 16

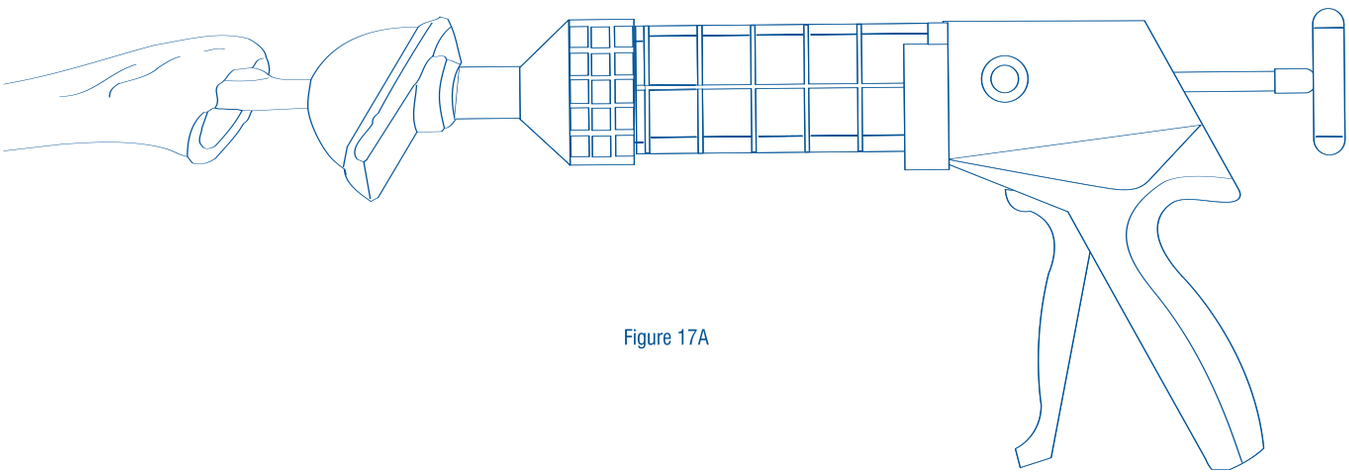


Figure 17A

10. Femoral Cementing

- The bone cement should be mixed in a mixing bowl for 1 minute and then poured into the cement barrel, which should be left to stand for 30 seconds. Three mixes may be necessary for large femora. The nozzle is fixed to the barrel, the femoral seal and backing plate positioned, and the cement gun is primed.

  Cement is introduced in a retrograde (ie. from distal to proximal) fashion (Fig. 17A). As the cement reaches the upper part of the canal, the nozzle of the gun is cut off distal to the femoral seal.

  The femoral seal is then impacted forcibly onto the upper end of the femur, and the remaining cement is slowly pumped into the femur (Fig. 17B). This action will maintain a steady pressure to overcome the bleeding pressure inside the femur. When pressurisation is correctly performed, a steady extrusion of fat through the walls of the upper femur may be seen. Cement injection and pressurisation is continued until the viscosity of the cement starts rising. The femoral stem is then inserted.

  The aim should be to delay stem insertion as long as possible remembering that during stem insertion interface pressures in the canal are directly related to the viscosity of the cement.

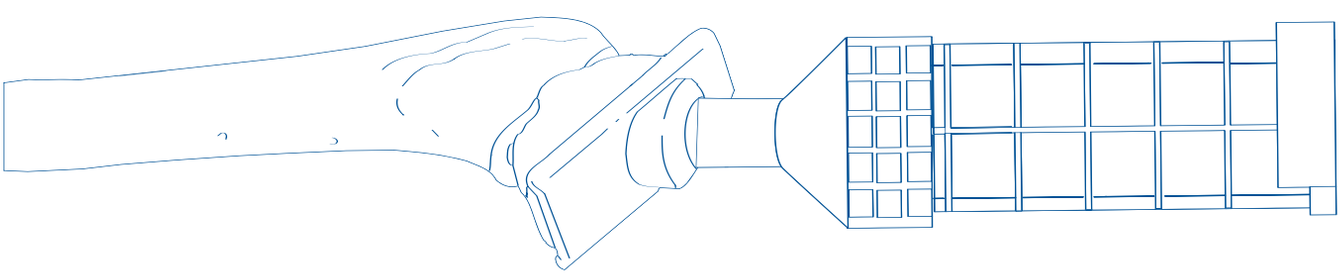


Figure 17B

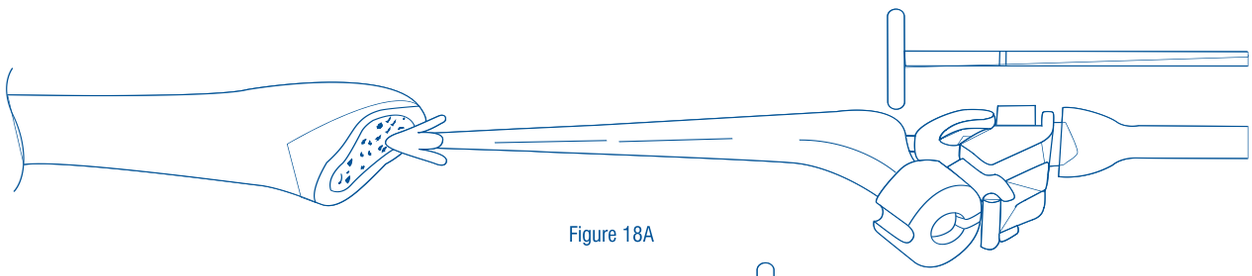


Figure 18A

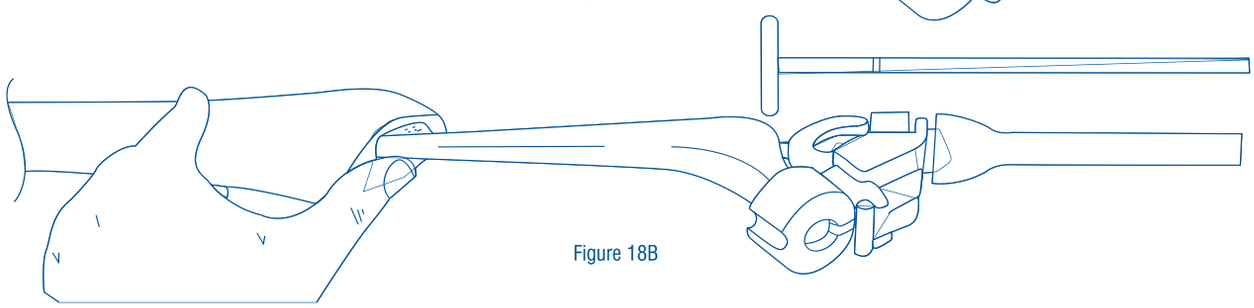


Figure 18B

11. Stem Implantation

- The selected stem is mounted on the introducer. It is important to note that the handle of the introducer is exactly in the mid-line of the stem and so the introducer and the stem can be lined up with the medullary canal of the femur. The stem introducer can be used with one hand, and has a smooth trigger action which releases the introducer pin from the dimple in the lateral shoulder of the stem implant.

  The stem is introduced through the proximal femoral opening closer to the posterior femoral cortex than the anterior, and aiming at the middle of the popliteal fossa if the posterior approach is used, or the patella if the lateral approach is used (Fig. 18A).

  The stem can be driven into the canal through the stem seal and its backing plate which should be held firmly in position on the cut surface of the femoral neck.

  Otherwise the stem is driven into place with the surgeon's thumb occluding the medial exit from the upper end of the femur between the stem and the calcar, to further pressurise the cement into the cancellous bone (Fig. 18B). During stem insertion, there should be further extrusion of fat through the walls of the femur.

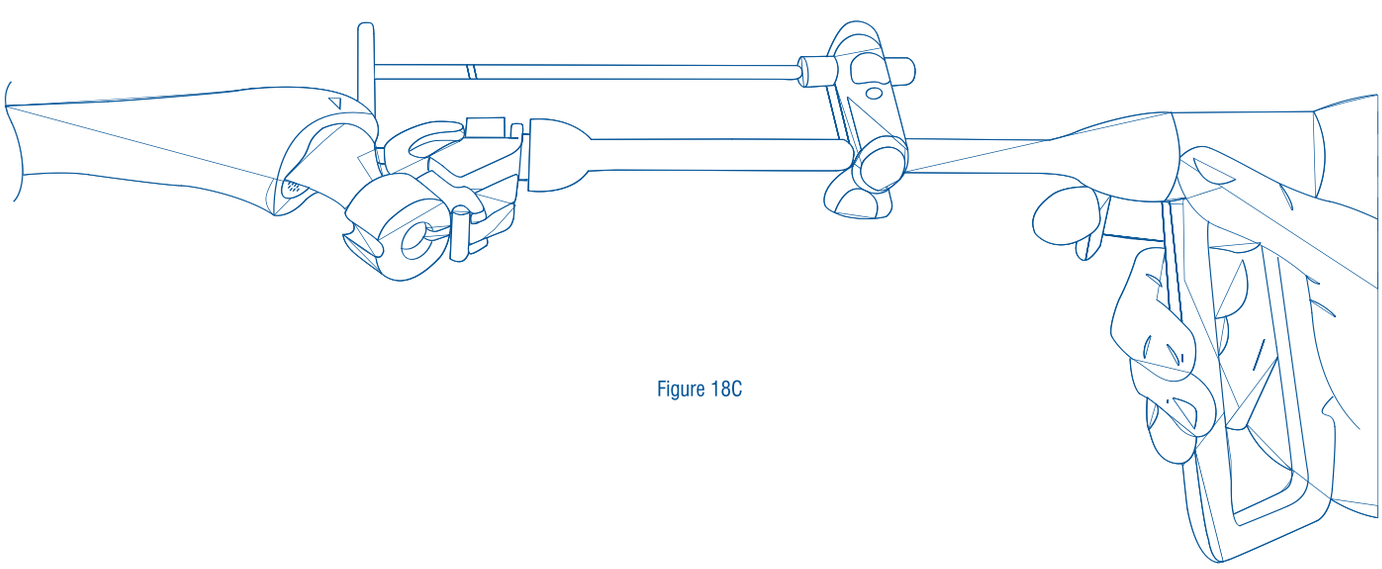


Figure 18C

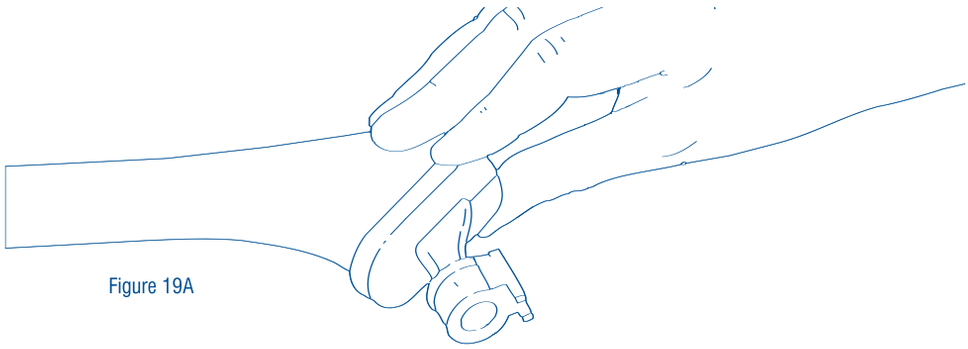


Figure 19A

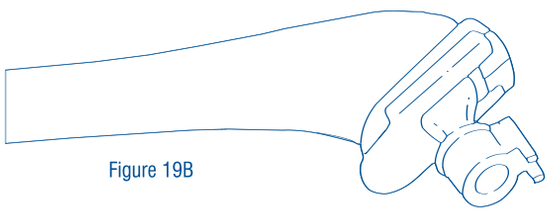


Figure 19B

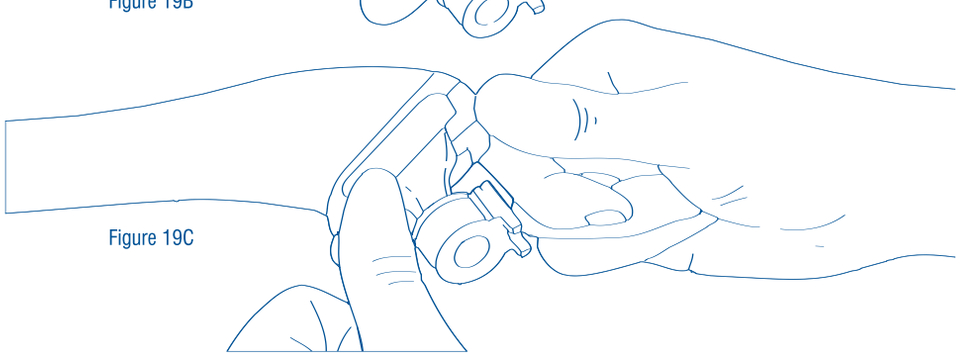


Figure 19C

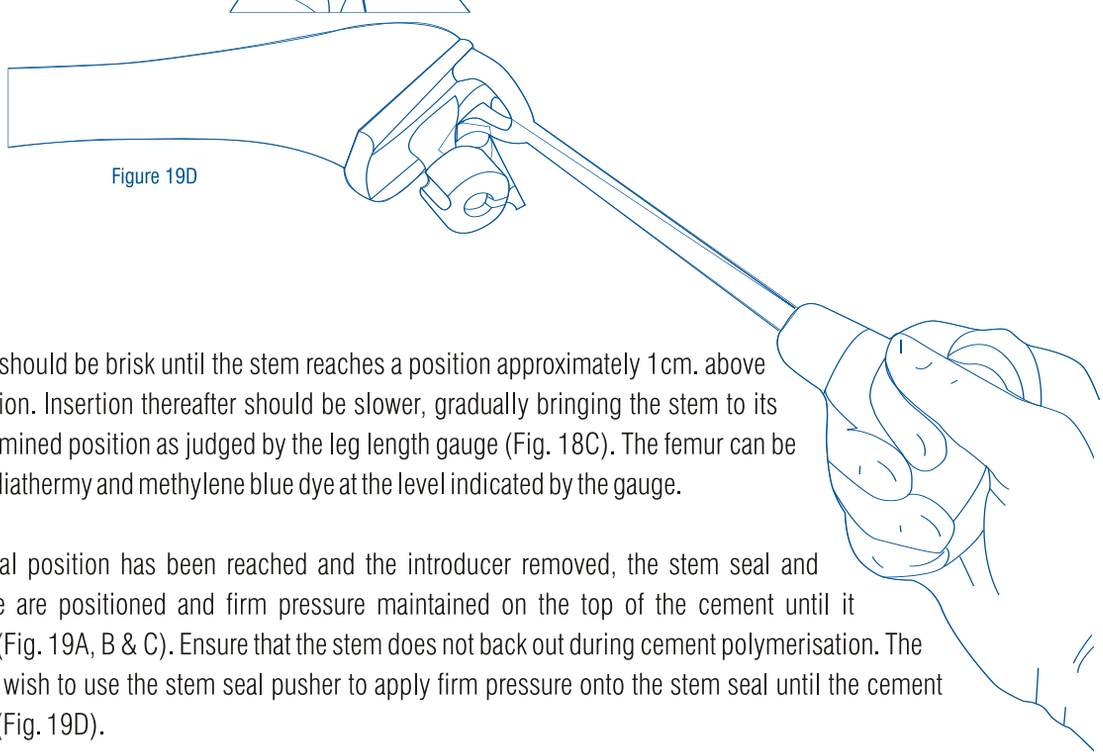


Figure 19D

- The insertion should be brisk until the stem reaches a position approximately 1cm. above its final position. Insertion thereafter should be slower, gradually bringing the stem to its final predetermined position as judged by the leg length gauge (Fig. 18C). The femur can be marked with diathermy and methylene blue dye at the level indicated by the gauge.

  When the final position has been reached and the introducer removed, the stem seal and backing plate are positioned and firm pressure maintained on the top of the cement until it polymerises (Fig. 19A, B & C). Ensure that the stem does not back out during cement polymerisation. The surgeon may wish to use the stem seal pusher to apply firm pressure onto the stem seal until the cement polymerises (Fig. 19D).

  The surgeon should remove all cement from the cut surface of the cortical calcar.

Figure 20A

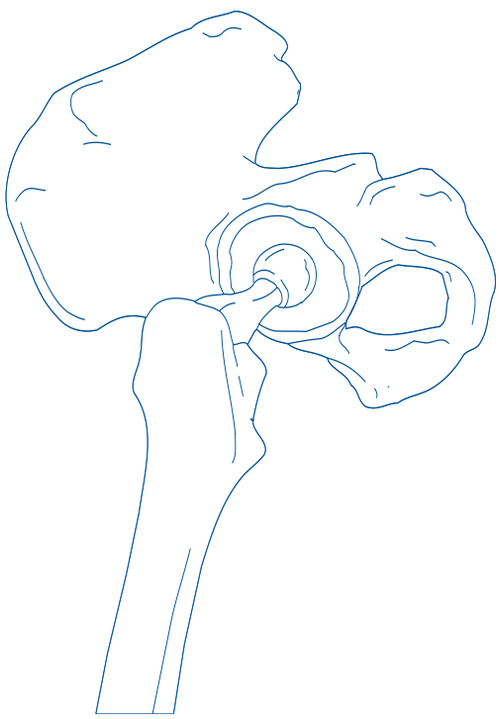


Figure 20B

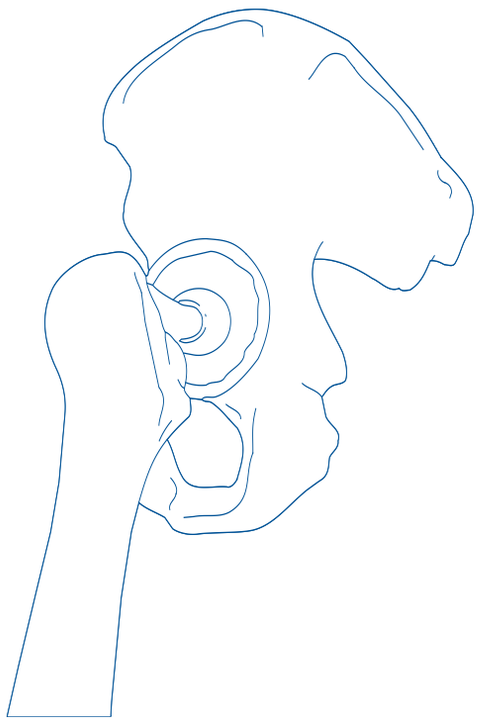


Figure 20C

12. Reduction

➢ The spigot protector is then removed and the spigot thoroughly cleaned.

A further trial reduction may be carried out using the appropriate trial heads on the Altius™ spigot. Checks are then made again for correct leg length and stability. Reduced and increased neck lengths are available. The appropriate size of femoral head is removed from its packaging and placed over the stem spigot. It is secured in place by firm blows with the palm of the hand. Alternatively, the head may be pushed on by hand & rotated 10^{0}. Neither excess force, impaction nor hard instruments should be used as this may damage the fine polished surface (Fig. 20).

DAY OF OPERATION

Encourage breathing exercises. Check that foot, ankle and quadriceps exercises are carried out hourly by the patient.

FIRST POST-OPERATIVE DAY

Supervise breathing and foot, ankle and quadriceps exercises. Begin resisted exercises for the un-operated leg and assisted active exercises for the operated leg, including external rotation and active hip abduction with the weight of the leg being taken by the physiotherapist. The patient is encouraged to do the movements with assistance from the physiotherapist. Avoid internal rotation, sitting erect or the use of too many pillows. Younger patients may stand on the first post-operative day.

SECOND POST-OPERATIVE DAY

Continue with breathing exercises, foot, ankle, quads and gluteal exercises. Remove the drains. The physiotherapist should help the patient to get out of bed, after ensuring that the bed is at the correct height. The patient should wear shoes. Knee flexion is encouraged with the patient sitting sideways on the edge of the bed. In getting into a standing position the patient should take as much weight as possible on the non-operated leg with support from the physiotherapist who should stand on the same side as the affected hip with a stick in the patient's opposite hand or another helper on that side if necessary. In the standing position the patient should be shown how to stand and walk. The patient should be encouraged to take normal steps, although the first walk should be kept within the patient's tolerance. Touch weight bearing is advisable except in the elderly. The patient must be taught to turn around without straining the hip in a rotatory position, and be taught how to sit and stand correctly from a chair. The physiotherapist should teach the patient how to get back into, and out of bed, and assist them to do so, preventing internal rotation and adduction of the hip during these manoeuvres.

THIRD POST-OPERATIVE DAY

All static exercises and breathing exercises are supervised. The patient may be taught to turn prone and is encouraged to lie prone for two periods of twenty minutes daily.

FOURTH POST-OPERATIVE DAY

Continue supervision of static exercises and breathing exercises. The physiotherapist should continue to supervise correct walking and the patient can increase the number and duration of the walks. The patient is instructed in getting into a sitting position on the toilet. The physiotherapist should start to teach the patient to lift the leg on to the bottom step of the stairs flexing the hip and knee whilst avoiding internal rotation.

FIFTH POST-OPERATIVE DAY

Continue supervision of static exercises. The patient should be able to walk to the toilet alone. The physiotherapist should start the patient walking up and down steps and generally increase walking. A post-operative X-ray is taken. The patient should be independent upon discharge and allowed home with suitable walking aids supplied by the occupational therapist. The patient should avoid excessive flexing of and internally rotating the hip.

POST-OPERATIVE FOLLOWUP VISITS

The first post-operative follow-up visit is usually two to three months after surgery. X-rays at this stage are only taken if bone grafting was performed. If the patient's condition is satisfactory at three months, the next appointment should be one year from the time of operation. X-rays should be taken. If these are satisfactory, further follow-up visits are not needed, unless the patient develops symptoms suggesting any problem with the arthroplasty. However, arrangements should be made for the arthroplasty to be viewed by X-ray two years from the time of the operation. Provided these films are satisfactory, no further films need be taken for seven to eight years, unless the patient develops symptoms suggesting problems with the arthroplasty. From eight years on, films should again be taken at two yearly intervals.

HEALTHCARE

ALTIUS™

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