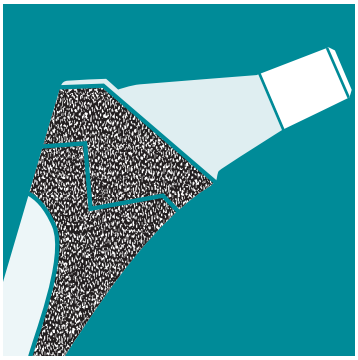
PROXILOCK®
HIP PROSTHESIS

PROXILOCK HIP PROSTHESIS



Surgical Technique for Primary Hip Arthroplasty

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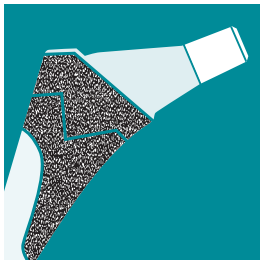
SURGICAL TECHNIQUE FOR PROXILOCK® * HIP PROSTHESIS



THIS SURGICAL TECHNIQUE DEVELOPED IN CONJUNCTION WITH:

Thomas O'Keefe, M.D.
Ann Arbor, Michigan

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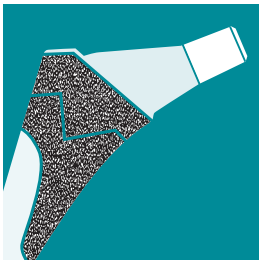


PREOPERATIVE PLANNING

Preoperative planning is an essential element of any safe and effective surgical procedure. Femoral stem size, level of femoral neck cut, proposed post-operative neck length and offset should be evaluated preoperatively by radiographic analysis. This also assures that the appropriate implant will be available at the time of surgery.

The overall objective of preoperative planning is the accurate placement of a femoral prosthesis.

Determination of Leg Length

Most patients have unequal limb lengths preoperatively. However, a single A/P radiograph of the pelvis will usually provide sufficient documentation of limb length differences to allow accurate surgical planning. More complex situations that involve pelvic obliquity, deformities of the knee, or foot and ankle may require standing long films of the lower extremity or CT evaluation of limb length.

Planned limb shortening of any significance usually necessitates a femoral osteotomy, advancement of the greater trochanter, or both, if proper post-operative soft tissue tension is to be achieved. Failure to consider this possibility may result in abductor laxity and post-operative hip dislocation.

A trochanteric osteotomy is usually not required when maintaining or lengthening the limb, but should be considered when the proximal femoral anatomy is severely distorted in order to facilitate the procedure.

Determination of Abductor Muscle Tension and Femoral Offset

The femoral offset is the perpendicular distance from the extended centerline of the femoral canal to the center of the femoral head. Intra-operative recreation of this distance is essential for normal postoperative abductor muscle tension and function. Hip instability, weakness and a gluteal gait are common unintended consequences of inattention to this detail of the preoperative assessment.

While the normal range of motion of femoral implant sizes allows for recreation of most anatomic positions, unusually large offsets and marked varus femoral neck angles may require an increase in the femoral neck length in order to achieve proper abductor length. Variations in the middle-lateral placement of the acetabular component influence the anatomic offset as well.

Component Size Selection/Templating

Accurate template estimation of prosthetic size requires an anterior-posterior and lateral radiograph of the proximal 20cm of the femur. An A/P view of the pelvis centered on the symphysis pubis is usually sufficient; however, an A/P of the involved side with the femur in internal rotation compensates for naturally occurring femoral anteversion and provides a better representation of the true medial to lateral metaphyseal dimension. Additionally, an A/P film taken with the patient in a seated position can overcome distortion of the proximal diaphysis in the presence of a hip flexion contracture. Similarly, a cross table lateral may be necessary in the stiff hip where limited motion decreases abduction in the frog leg position, magnifying the distal femur.

Radiographic magnification of the femur depends on the distance from the x-ray source to the film and upon the distance from patient to cassette. Average magnification on most x-rays is 20%. Large and obese patients may have greater magnification and small, thin patients, less. *ProxiLock* templates accommodate a standard magnification of 20% (templates of 15% and 10% magnification are available by special order). The magnification of a specific film may be determined by using a standard marker on each cassette.

The initial templating begins with the A/P radiograph. Superimpose the acetabular template sequentially on the pelvic x-ray image (Fig. 1) with the acetabular component in approximately 40º of abduction. Range of motion and hip stability are optimized when the socket is placed in approximately 35º - 45º of abduction. Assess several sizes to estimate which acetabular component will provide the best fit for maximum coverage. In most cases, select the largest component possible, being certain that the outside diameter isn't too large to seat completely in the acetabulum. (Refer to the Zimmer *Trilogy*® Acetabular System surgical technique for further details on acetabular reconstruction.) Consider the position and thickness of the acetabular component in estimating the optimum femoral neck length to be used. (To simplify this, the acetabular templates are on a separate acetate sheet from the femoral templates.) Mark the acetabular size and position, and the center of the head on the x-ray films. This allows any femoral component to be matched with the desired acetabular component by placing the femoral template over the acetabular template. This will provide the best

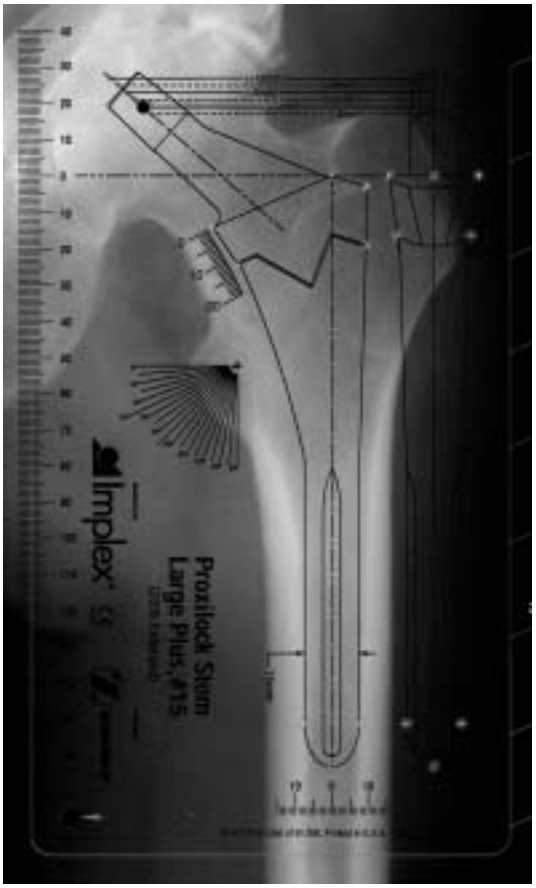
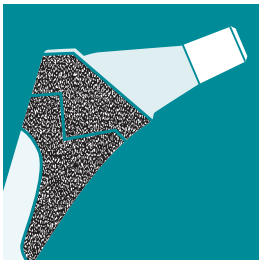


Fig. 1

estimation of femoral component size and head/neck length necessary to achieve the correct leg length.

The *ProxiLock* Hip System has two head diameters: 22mm and 28mm. In most patients with an average-sized acetabulum, consider a 28mm femoral head. This will allow the use of an acetabular component with an outside diameter small enough to seat completely in the bone while also allowing for a polyethylene liner of sufficient thickness.

In special circumstances, such as the treatment of small patients and small acetabular volume, it is preferable to use a 22mm diameter head to allow for adequate polyethylene thickness.



The specific objectives in templating the femoral component include:

1. determining the anticipated size of the implant to be inserted, and
2. determining the height of the implant in the femur and the location of the femoral neck osteotomy.

To begin templating, select the appropriate femoral template. The *ProxiLock* Prosthesis is available in titanium HA and cobalt chromium beaded versions, both available in eight sizes (10mm-17mm). The femoral templates show the neck length for each of the head/neck combinations (-3mm to +12mm, depending on head diameter).

To estimate the femoral implant size on the A/P radiograph, and then check the stem size on the lateral radiograph. Superimpose the template on the medullary canal and estimate the appropriate size of the femoral stem. The stem of the femoral component should fill, or nearly fill, the medullary canal on the A/P x-ray film. Next, assess the fit of the body in the metaphyseal area. The medial portion of the body of the component should fill the proximal metaphysis as fully as possible, compatible with the anatomic endosteal contours of that region.

Next, check the fit of the stem on the lateral x-ray film. If the lateral radiograph reveals that the A/P dimension of the medullary canal is greater than the mediolateral dimension shown on the A/P film, it may be advantageous to increase the size of the stem to better fill the medullary canal. Template the next larger size femoral component on the A/P x-ray film to determine the amount of cortical bone that would be removed by reaming to this size. The cortical thickness of the walls must be great enough to allow for additional reaming. If a larger stem would better fill the medullary canal, it is preferable to insert the larger stem. This can be accomplished by enlarging the isthmus in the M/L dimension with intramedullary reamers. When a larger size is chosen to better fill the isthmus on the lateral x-ray film, re-evaluate the A/P x-ray film to ensure that the fit of the proximal and distal stem is acceptable.

Careful attention during this process helps the surgeon achieve the goal of implanting a stem that will provide maximum stability and contact with the host bone.

After establishing the proper size of the femoral component, determine the height of its position in the proximal femur and the amount of offset needed to provide adequate abductor muscle tension. Generally, if the leg length and offset are to remain unchanged, the center of the head of the prosthesis should be at the same level as the center of the femoral head of the patient's hip. This should also correspond to the center of rotation of the templated acetabulum. To lengthen the limb, raise the template proximally. To shorten the limb, shift the template distally.

Once the height has been determined, note the distance in millimeters from the top surface of the lesser trochanter to the level of the stem/neck transition by using the millimeter scale on the template.

Proximal/distal adjustments in prosthesis position can reduce the need for a femoral head with a skirt. (The skirted heads allow less range of motion than the nonskirted heads which may increase the chance of dislocation.)

The template is designed to indicate the location and angle of the appropriate calcar resection. Mark the radiograph using the marking pen cutouts provided.

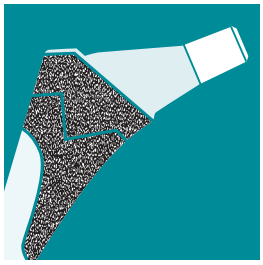
Initiating Femoral Reaming

The next important step in preoperative planning is to determine where to initiate reaming of the femoral canal to place the prosthesis in a neutral position within the femur. Conceptually, reaming for a porous or HA femoral component is more comparable to reaming for a blind intramedullary nail than to preparing the femur for inserting a traditional cemented total hip femoral component. Failure to properly ream the femur in line with the longitudinal axis of the medullary canal has two major disadvantages: First, it risks placing the femoral component in varus alignment and, second, it risks eccentric reaming with cortical thinning or even perforation.

When templating the femur on the A/P x-ray view, the surgeon should check the fit of the component in the metaphyseal and diaphyseal areas. Using the A/P template, extend the center line up to the greater trochanter. This is the approximate point to initiate reaming.

The use of the lateral templates superimposed on the frog-leg lateral x-ray film is essential for preoperative planning. Only in the lateral view can the anterior curvature of the femur be appropriately assessed.

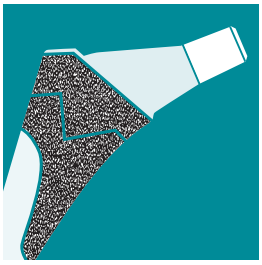
Templating the lateral view of the femur shows how the femoral stem will fit in the medullary canal and what areas will need to be preferentially reamed in order to reduce the curvature in that area. Typically, bone must be removed from the thick posterior cortex of the medullary canal. It is also helpful to remove some bone from the proximal portion of the anterior surface of the metaphyseal region of the femur. The combined removal of posterior cortex in the medullary canal and anterior bone in the proximal part of the metaphysis effectively redirects the medullary canal. This preferential reaming reduces the arc of the femur or, in effect, straightens the anterior bow of the medullary canal.



Reaming also substantially reduces the disparity between the anteroposterior and mediolateral dimensions of the medullary canal. The lateral template helps predict which size stem is most likely to be used, as well as the necessary amount and the preferred site of the reaming.

Another important aspect of the use of the lateral template becomes apparent when one views the overlap of the template in its projected alignment with the posterior portion of the femoral neck. In some cases, the posterior aspect of the femoral neck will underlie the outline of the femoral component. This indicates that the femoral component would be prevented from advancing down the femoral canal unless a portion of the posterior neck were removed. In this circumstance, a portion of the posterior femoral neck must be excised before initiating the reaming process in the femoral canal.

Thus, templating in the lateral view locates the A/P starting point for reaming and shows the surgeon how far into the greater trochanter reaming must start to eliminate varus or valgus malposition.



SURGICAL TECHNIQUE

Incision and Exposure

In total hip arthroplasty, exposure can be achieved through a variety of methods based on the surgeon's preference. The *ProxiLock* Prosthesis can be implanted using a variety of surgical approaches, including the posterolateral, straight lateral, or transtrochanteric approaches.

Determination of Leg Length

Establish landmarks and obtain measurements before dislocation of the hip so that, after reconstruction, a comparison of leg length and femoral shaft offset can be obtained. From this comparison, adjustments can be made to achieve the goals established during preoperative planning. There are several methods to measure leg length.

One method is to fix a leg length caliper to the wing of the ilium. Then, take baseline measurements to a cautery mark at the base of the greater trochanter while marking the position of the lower limb on the table.

Osteotomy of the Femoral Neck

A common technical error in total hip replacement surgery is insertion of the femoral component in a varus position. The likelihood of this error can be reduced if visualization of the posterior femoral neck is improved. To accomplish this, remove all of the remaining soft tissue from the posterior femoral neck, exposing the intertrochanteric crest and the junction between the femoral neck and greater trochanter.

Release some of the inferior capsule to expose the lesser trochanter. When the ideal position of the appropriately selected femoral component was determined during the preoperative planning, the distance between the top surface of the lesser trochanter and the proximal level of the porous or HA stem surface was noted. Use this information to determine the level for the femoral neck osteotomy.

Dislocate the hip in flexion, internal rotation, and adduction. Place the tibia perpendicular to the femur. Then direct the foot toward the ceiling, which will deliver the proximal femur into the wound.

The Osteotomy Guide allows the estimation of the resection line based on the preoperative templating process. Superimpose the Osteotomy Guide (Fig. 2) on the femur. The Osteotomy Guide has markings indicating 10mm, 15mm, and 20mm distances from the lesser trochanter as well as holes to estimate the femoral head center of rotation, which frequently, but not always, corresponds to the level of the tip of the greater trochanter. Once the proper height is found, use electrocautery to inscribe a

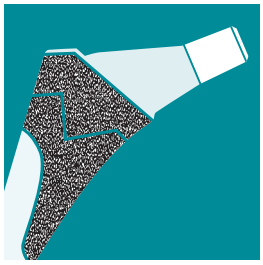
Fig. 2

line across the femoral neck parallel to the undersurface of the Osteotomy Guide.

The Osteotomy Guide sets the resection angle at 25° and at a level such that the stem center of rotation corresponds to the tip of the greater trochanter or anatomic head center.

There are two criteria for positioning the guide. First, determine the varus or valgus relationship so the center line of the femoral stem overlies the diaphyseal midline bisecting the longitudinal axis of the medullary canal. Palpate both the medial and lateral cortices of the femur in the region of the isthmus through the bulk of the vastus lateralis muscle group to determine the distal position of the Osteotomy Guide.

Second, once neutral alignment has been determined, move the template proximally or distally to the correct height, as determined in preoperative planning. The Osteotomy Guides have a linear scale starting at the collar and running distally along the medial edge. This scale is identical to that used preoperatively on the acetate template. Align the hole with the center of rotation of the femoral head which corresponds to the acetate templated head/neck noted.

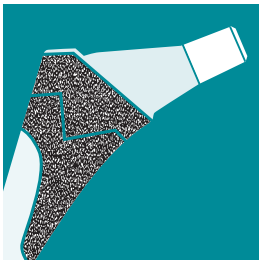


This alignment of the Osteotomy Guide would be appropriate for most femurs that have a neck shaft angle of 135°. However, if the femur has a neck shaft angle more than or less than 135°, adjustments to the position of the Osteotomy Guide should be made. To achieve the templated head center, adjust the osteotomy guide either proximally or distally. At that point, use electrocautery to scribe a line across the femoral neck parallel to the top surface of the Osteotomy Guide.

Using the scribed line as a guide, perform the osteotomy of the femoral neck. To prevent possible damage to the greater trochanter, stop the cut as the saw approaches the greater trochanter. Remove the saw and either bring it in from the superior portion of the femoral neck to complete the osteotomy cut, or use, an osteotome to finish the cut.

Preparation of the Femur

To appropriately insert the femoral prosthesis, excellent exposure of the proximal femur must be obtained. The femur should extend out of the wound, and soft tissue should be removed from the medial portion of the greater trochanter and lateral portion of the femoral neck. It is crucial to adequately visualize this area so the correct insertion site for femoral reaming can be located. Refer to the preoperative planning to identify the midfemoral shaft extension intraoperatively as viewed on the A/P and lateral radiographs. This is usually in the area of the piriformis tendon insertion in the junction between the medial trochanter and lateral femoral neck.



Insert the Starter Reamer into the area of the piriformis fossa and pass it down the canal (Fig. 3). This will help in preparing the femoral canal.

Fig. 3

Alternatively, use the Box Osteotome to osteotomize the medial portion of the greater trochanter (Fig. 4). This also will facilitate access to the canal and ensure proper alignment of the femoral instruments to avoid varus placement of the stem.

Fig. 4 Alternative Trochanteric Preparation

Insert the Trochanteric Reamer into the piriformis fossa and pass it into the canal (Fig. 5). The cylindrical portion of the reamer will shape the medial aspect of the greater trochanter, facilitating access to the canal and establishing the proper axial placement of the Proximal Femoral Shaver, the Stem Provisional, and the final stem component. Ensure lateralization of the Trochanteric Reamer so that sufficient resection of the Greater Trochanteric Bed is achieved.

Fig. 5

The Cylindrical Reamers are available in sizes from 9mm - 17mm in 1mm increments. Begin reaming the distal canal using the 9mm Cylindrical Reamer (Fig. 6). Insert the reamer until the top of the gold colored area is aligned with the most lateral aspect of the neck resection. Be sure that the reamer is aligned with the central axis of the femoral canal to help prevent the stem from being implanted in either a varus or valgus position. Continue reaming in 1mm increments until the reamer engages the endosteal cortex.

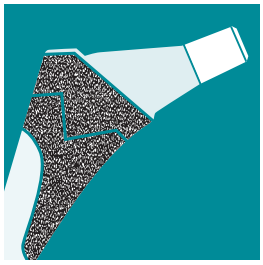
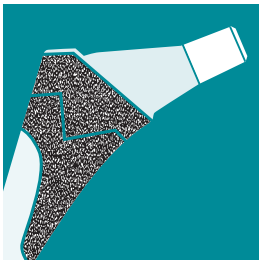


Fig. 6

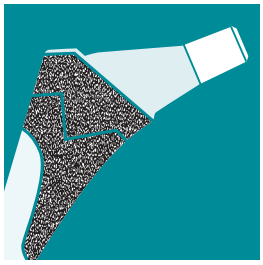


Frequently, the metaphyseal and diaphyseal femoral canal geometries are not proportional. This may be revealed through a discrepancy between sizes of the reamer and the final shaver. The size of the stem chosen for implantation should always match the size of the last Femoral Shaver used.

Fig. 7

Begin shaving the femoral canal by inserting the 9mm Femoral Shaver. Be careful to align the shaver accurately during impaction and extraction. Malalignment can result from using an undersized stem or from a femoral fracture. Insert the shaver until it is fully seated, usually 2mm-3mm below the resection level (Figs. 7 & 8). The Femoral Shaver fills the metaphysis at the neck resection level in the M/L plane only.

Fig. 8



The Femoral Shavers incorporate two standoffs on both the anterior and posterior sides to facilitate visualization of the predicted fit of the *ProxiLock* Stem (Fig. 9).

Use progressively larger shavers in order to minimize the amount of bone removal with each pass. This will reduce the risk of femoral cracking. The Proximal Femoral Shavers are color coded to coincide with the color of the Stem Provisionals and the package label color for the implant.

If the final size shaver is smaller than planned, a varus alignment is usually the cause. To correct the alignment, it may be necessary to lateralize the shaver into the medial aspect of the greater trochanter to achieve proper alignment.

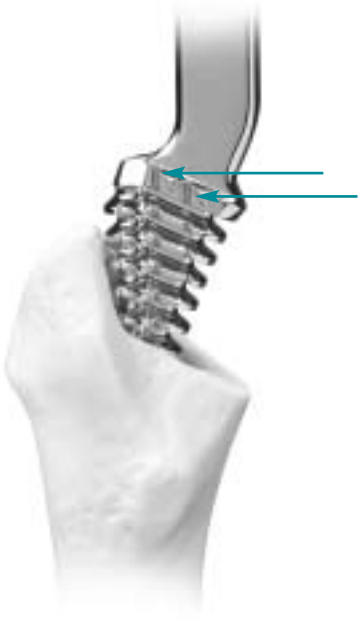


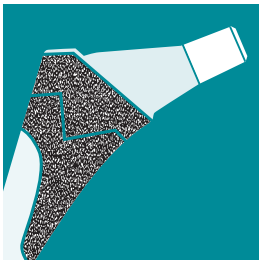
Fig. 9

Trial Reduction

The Stem Provisionals are color-coded to coincide with the size of the Proximal Femoral Shaver and the label on the implant package. The Stem Provisional geometry is 0.5mm per side smaller than the *ProxiLock* Stem. This enables a more stable construct for a more accurate trial reduction while minimizing the possibility of damage to the prepared endosteal bone.

Select the Stem Provisional based on the size and color of the last Proximal Femoral Shaver used. Assemble the Stem Provisional Handle to the Stem Provisional by pulling up on the distal spring-loaded knob so the guide post retracts into the end of the instrument. Align the lateral hole at the end of the instrument with the center pin on the Stem Provisional (Fig. 10). Release the knob so the guide post engages and locks into the medial hole of the provisional. The guide post must be securely engaged so the handle is flush with the Stem Provisional.

Fig. 10



Insert the Stem Provisional into the prepared femoral canal. The cutting surface of the provisional accurately shapes the 14° included taper of the stem in the most proximal metaphyseal bone by crushing looser cancellous bone near the cortex. Impact until the Stem Provisional does not advance and appears secure.

Disconnect the Stem Provisional Handle from the Stem Provisional by retracting the distal spring-loaded knob. This will disengage the interlocking pin from the medial hole in the Stem Provisional.

If the Stem Provisional is seated below the resection level, use the Calcar Planer to remove the excess femoral neck down to the level of the Stem Provisional (Fig. 11).

Fig. 11

Place the appropriate color-coded Provisional Neck onto the corresponding Stem Provisional. **Colors must match.** As determined in preoperative planning, select the Femoral Head Provisional with the appropriate neck length extension (-3mm through +12mm) and place it onto the trunnion of the Provisional Neck (Fig. 12).

Reduce the joint and check the range of motion and stability.

Fig. 12

Remove the Femoral Head Provisional and Neck Provisional. Reconnect the Stem Provisional Handle to the Stem Provisional by snapping the quick-connect guide post into the medial hole of the provisional. Then use the Slotted Mallet to extract the provisional (Fig. 13).

Note: If an alternative extraction method is preferred, the Stem Extractor can also be threaded into the lateral hole of the Stem Provisional.

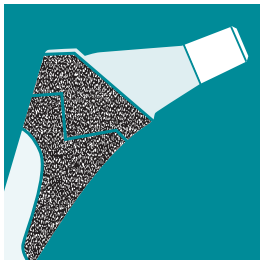
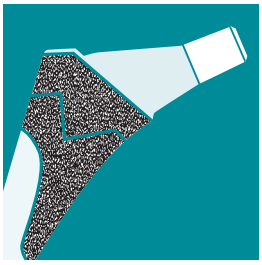


Fig. 13

Neck Length Extension	CoCr 22mm	CoCr 28mm	Zirconia Ceramic 28mm
-3mm		✔	
+0mm	✔	✔	✔
+3mm	✔	✔	✔
+6mm	✔	✔	✔
+9mm		✔	
+12mm		✔	

ProxiLock Stem Size	Base Neck Length (mm)	Head Offset (mm)
10	24	32
11	30	37
12	36	43
13	36	45
14	36	46
14+	42	50
15	42	52
16	42	53
17	48	59



Implantation

Insert the stem into the canal. Each stem incorporates a drive hole in the proximal lateral region. Use the bullet-nose Stem Impaction Handle (Fig. 14) in this drive hole to assist in the insertion of the stem into the canal.

Attach the Femoral Head Provisional and perform a final trial reduction to confirm the appropriate neck length extension, assess range of motion, and check for impingement areas.

Remove the Femoral Head Provisional, thoroughly clean the trunnion of the stem, and remove any debris. Select the appropriate femoral head component and place it on the stem. Note the color-coding on the package label to confirm that the outer diameter of the head is compatible with the inner diameter of the acetabular component.

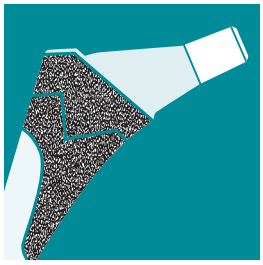
Impact the femoral head component onto the stem trunnion with two or more moderate blows of the Head Impactor (Fig. 15). Be careful not to contact the bearing surface of the head component with any hard, sharp, or metal objects.

Note: If inserting a ceramic head, attach it to the femoral stem by hand, using firm pressure and a slight twist.

Fig. 14

Fig. 15

Closure and Postoperative Management

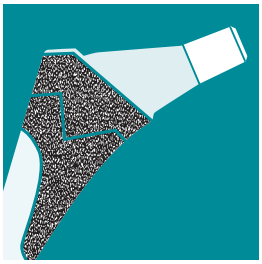


After obtaining hemostasis, insert a *Hemovac*® Wound Drainage Reinfusion Device or if the *OrthoPAT*®* Autotransfusion System was used perioperatively, continue its use postoperatively and close the wound in layers.

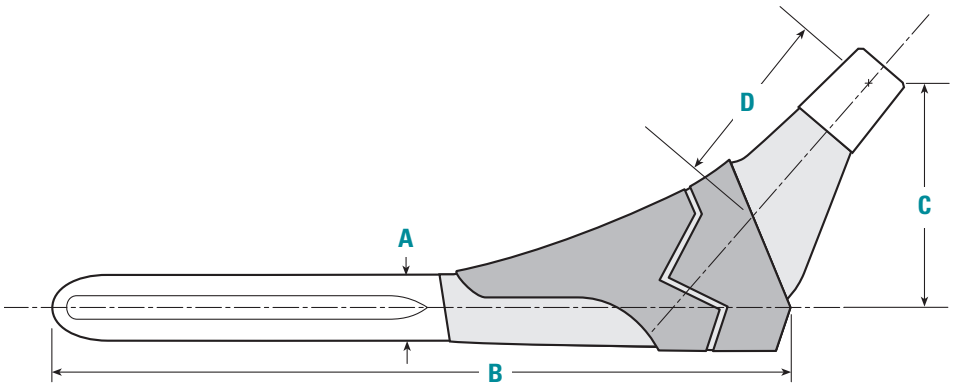
The postoperative management of patients with *ProxiLock* Hip Implants is determined by the surgical technique, patient's bone quality, fit of the implant, and the surgeon's judgement.

Fifty percent weight bearing using two crutches or a walker for six weeks is generally recommended for patients with bone ingrowth implants. Over the next six to eight weeks there may be a reduction in external support and an incremental increase in weight bearing.

* OrthoPAT is a registered trademark of Haemonetics Corporation



PROXILOCK HIP PROSTHESIS



Titanium HA Coated

Prod. No.	Stem Size	A Distal Stem Dia.	B Stem Length	C Head Offset	D Std. Base Neck Length
4110-10-24	10	10mm	108mm	32mm	24mm
4110-11-30	11	11mm	119mm	37mm	30mm
4110-12-36	12	12mm	130mm	43mm	36mm
4110-13-36	13	13mm	141mm	45mm	36mm
4110-14-36	14	14mm	152mm	46mm	36mm
4110-14-42	14+	14mm	152mm	50mm	42mm
4110-15-42	15	15mm	163mm	52mm	42mm
4110-16-42	16	16mm	163mm	53mm	42mm
4110-17-48	17	17mm	163mm	59mm	48mm

Cobalt Chromium

Prod. No.	Stem Size	A Distal Stem Dia.	B Stem Length	C Head Offset	D Std. Base Neck Length
4120-10-24	10	10mm	108mm	32mm	24mm
4120-11-30	11	11mm	119mm	37mm	30mm
4120-12-36	12	12mm	130mm	43mm	36mm
4120-13-36	13	13mm	141mm	45mm	36mm
4120-14-36	14	14mm	152mm	46mm	36mm
4120-14-42	14+	14mm	152mm	50mm	42mm
4120-15-42	15	15mm	163mm	52mm	42mm
4120-16-42	16	16mm	163mm	53mm	42mm
4120-17-48	17	16mm	163mm	59mm	48mm

CE 0120

ProxiLock Instrumentation

Prod. No.	Description
4202-000-01	General Instrument Set

Cobalt Chromium Femoral Heads

Prod. No.	OD Size	Neck Length
4100-22-02	22mm	+0
4100-22-03	22mm	+3
4100-22-04	22mm	+6
4100-28-01	28mm	-3
4100-28-02	28mm	+0
4100-28-03	28mm	+3
4100-28-04	28mm	+6
4100-28-05	28mm	+9
4100-28-06	28mm	+12

Zirconia Ceramic Femoral Heads

Prod. No.	OD Size	Neck Length
4101-28-02	28mm	+0
4101-28-03	28mm	+3
4101-28-04	28mm	+6

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Please refer to package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

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