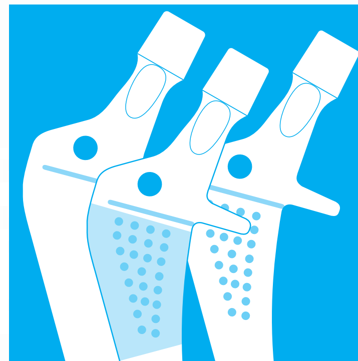
VerSys™ HIP SYSTEM

VERSYS CEMENTED, CEMENTED PLUS, AND CEMENTED CT HIP PROSTHESES



Surgical Technique for Primary Hip Arthroplasty

SURGICAL TECHNIQUE FOR VERSYS CEMENTED, CEMENTED PLUS, AND CEMENTED CT HIP PROSTHESES

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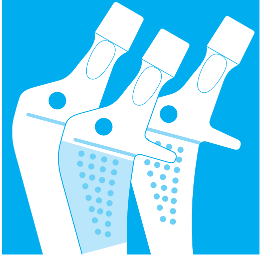
Please refer to the package insert for complete product information, including contraindications, warnings, and precautionary information.

Various components of the *VerSys* Hip System are covered by one or more of the following: U.S. Patents 4,281,420; 4,336,618; 4,491,987; 4,795,472; 4,963,155; 5,013,324; 5,018,285; 5,089,003; 5,156,624; 5,171,324; 5,192,323; 5,326,362; 5,480,453; 5,496,375; 5,569,255.
Other U.S. and foreign patents pending.



DESIGN PHILOSOPHY

The *VerSys* Hip System cemented stems represent a major advance in optimal placement and fixation of the femoral stem. The rasp system allows preparation of a bony bed into which the prosthesis can be inserted with a symmetrical cement mantle at all levels. The new aggressive taper of the distal tip helps reduce the strains in the cement mantle around the distal tip. The addition of an external distal centralizer helps centralize the implant distally. The *V-Lign*™ Proximal Centalizer and Proximal Sleeve Centralizer are innovations that aid in the proximal centralization of the stem. The stem geometry enhances stability in both frontal and sagittal planes. The stem is prepared with a variety of surface finishes to accommodate the latest research in promoting a stable and enduring cement/stem interface. The option of standard and extended offset implants allows for soft tissue stability without increasing leg length.

PREOPERATIVE PLANNING

The key to successful implantation is accurate preoperative planning. Effective preoperative planning allows the surgeon to predict the impact of different interventions in order to perform the joint restoration in the most accurate and safe manner.

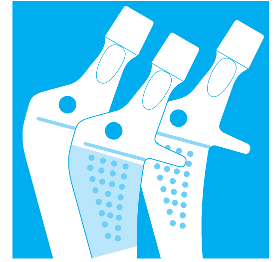
The objectives of preoperative planning include:

1. determination of leg length,
2. establishment of appropriate abductor muscle tension and femoral offset,
3. determination of anticipated component sizing,
4. determination of the level of the osteotomy above the superior border of the lesser trochanter, and
5. determination of lateralization into the trochanteric bed to achieve neutral alignment of the implant.

The overall objective of preoperative planning is to enable the surgeon to gather anatomic parameters which allow accurate intraoperative placement of the femoral implant.

In femoral templating, it is important to appreciate that magnification of the size of the femur will vary depending on the distance from the x-ray source to the film and the distance from the patient to the film. The *VerSys* Hip System templates use standard 20 percent magnification, which is close to the average magnification on most clinical x-rays. Larger patients or more obese patients may have magnification greater than 20 percent because their osseous structures are farther away from the surface of the film. To determine the magnification of any x-ray film, use a standardized marker at the level of the femur when marking the x-ray film.

Mark the center of rotation of the femoral head on the preoperative x-ray. Overlay the template onto the A/P x-ray so the midline of the implant is aligned over the anatomical axis of the femoral medullary canal. The template is then moved superior or inferior so the head level marked +0mm is superimposed on the center of rotation of the femoral head (Fig. 1). Choose the appropriate size of stem so that the rasp envelope fills the femur up to the endosteal cortices. On the lateral view, the rasp envelope should fill the canal up to the endosteal cortex.



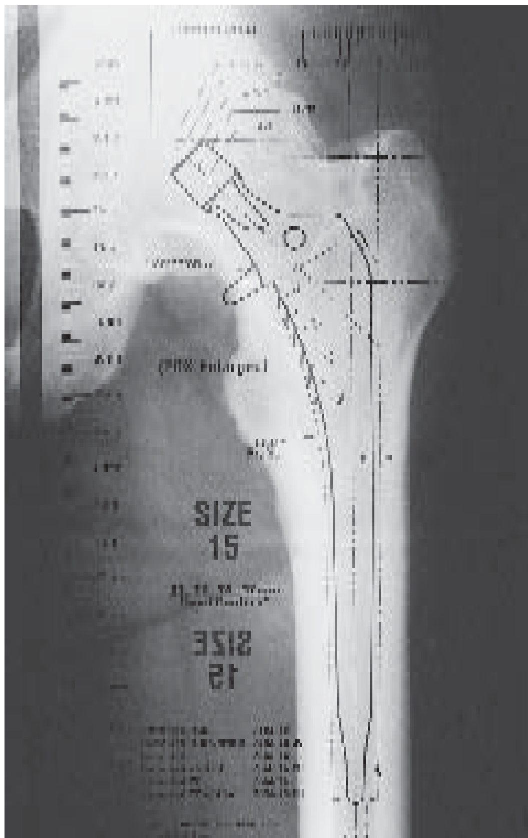


Fig. 1

The *VerSys* Cemented stems are available in both standard and extended offset options. This enables proper restoration of joint kinematics in hips that have a more natural varus configuration proximally, without increasing the leg length. Femoral templates are available for each of the six standard offset implants (size 12 through size 17) and are color-coded by system family (red designates Cemented family). The four templates in the middle range of sizes (size 13 through size 16) are marked to show the head centers for both the standard and extended offsets.

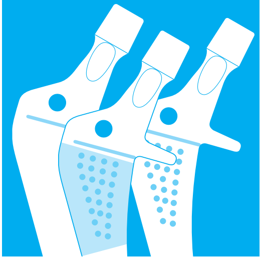
The neck osteotomy level can be marked on the x-ray once the template has been properly superimposed. Head centers for each head-neck combination are shown in 3.5mm increments from -3.5mm to +10.5mm (depending on head diameter). By using the "STANDARD" (+0) level to determine the level of the osteotomy cut, the surgeon has the option of using either a standard (+0) head or one that is -3.5mm shorter or +3.5mm longer than the standard (+0) without having to use a femoral head with a metal skirt. If more length is needed at the time of surgery, two additional femoral heads are available whose neck lengths are +7mm and +10.5mm longer than the standard (+0) neck length. These heads (with the two longest neck lengths) have metal skirts. Use of femoral heads with metal skirts will reduce the range of motion of the joint after implantation.

SURGICAL TECHNIQUE

Incision

In total hip arthroplasty, exposure can be achieved through a variety of methods. The *VerSys* Cemented implant can be inserted with equal ease using a posterolateral, anterior (straight) lateral or transtrochanteric approach.

The most common is a posterolateral approach. Following the posterolateral approach of Kocher-Langenbeck, position the patient on the operating table in the true lateral position. This position must be accurately determined and firmly held since the orientation of the acetabular component will relate to this position. Flex the bottom hip and knee at approximately 45 degrees, assuring that the leg is well padded and secured to the table. Prepare the skin in the usual way and drape the lower extremity. Center the incision over the posterior aspect of the greater trochanter and extend it paralleling the femur for



about four inches. Angle the proximal portion of the incision posteriorly and superiorly at 45 degrees in the direction of the posterior inferior iliac spine and continue it approximately four inches in this direction from the trochanter. The incision can be extended in either direction depending on the unique requirement of each operation.

Divide the fascia lata in line with the skin incision through the full length of the wound. Begin this division of the fascia lata at the distal end of the incision, particularly if there has been previous surgery in the area of the hip. Identification of the tissue planes is easiest at the distal end of the wound.

Exposure of the Hip Joint

Develop the exposure of the posterior capsule. To facilitate this, place the leg in internal rotation. The key landmark for division of the short external rotators is the tendon of the piriformis muscle. This tendon runs parallel to the posterior border of the gluteus medius and can be readily palpated as it approaches the posterior superior portion of the greater trochanter. Retract the gluteus medius superiorly and identify the tendon of the piriformis.

Determination of Leg Length

Establish landmarks and obtain measurements before dislocation of the hip so that a comparison of leg length and femoral shaft offset can be obtained after reconstruction. 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 attach the leg length caliper to the wing of the ilium, just below the anterior-superior iliac spine. Then place a reference point on the greater trochanter.
Make the initial measurement in an immobilized reproducible position and mark the position of the lower limb on the table.

Osteotomy of the Femoral Head

After exposing the proximal femur, superimpose the Osteotomy Guide on the proximal femur (Fig. 2). The longitudinal axis of the guide should be parallel to the longitudinal axis of the femur.
The hole labeled "STD" refers to the standard offset implants. The hole labeled "EXT" refers to the extended offset implants. All holes on the osteotomy guide refer to the +0 head center. (The "REV" and "LD" markings correspond to the offsets for the revision and low demand/fracture implants, respectively. These marks must be

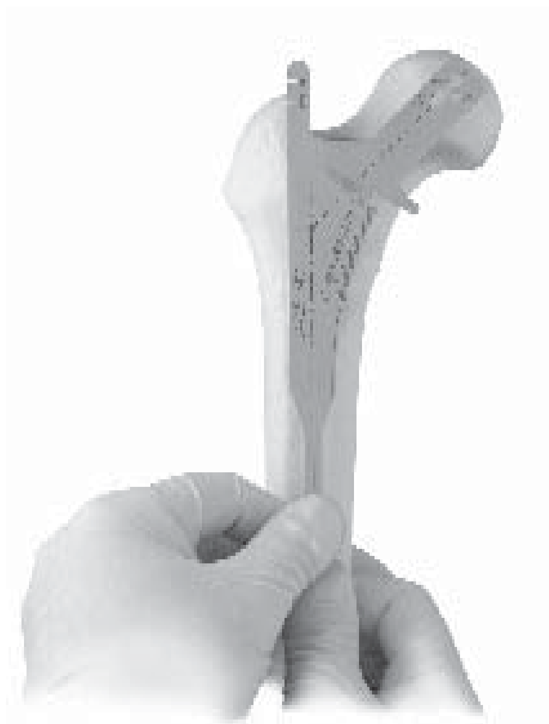
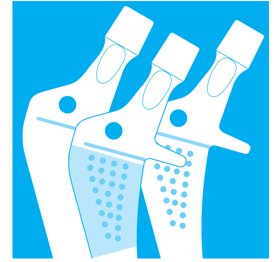


Fig. 2

disregarded when implanting a *VerSys* primary cemented stem.) On the preoperative x-ray, record the distance from the lesser trochanter to the center of rotation of the head bilaterally by using the magnified ruler provided on the side of each template. This is a useful guide to reestablish the correct leg length. At surgery, a ruler can be used to measure the distance from the lesser trochanter to the center of rotation of the natural femoral head. The tip of the greater trochanter should coincide with the mark designated as "S" (for standard) on the lateral edge of the Osteotomy Guide. (The "R" and "L" markings correspond to the revision and low demand/fracture implants, respectively. These marks must be disregarded when implanting a *VerSys* primary cemented stem.)

Mark the level of the neck osteotomy with either a saw or methylene blue. Note that the angle of the osteotomy cut is 60 degrees to the long axis of the femur (Fig. 3). The neck osteotomy should be made with a reciprocating saw and cut in the neutral plane. Do not attempt to build anteversion into the cut as the Calcar Planer will later assure a proper final surface, both anteriorly and posteriorly, on which the collar will rest.



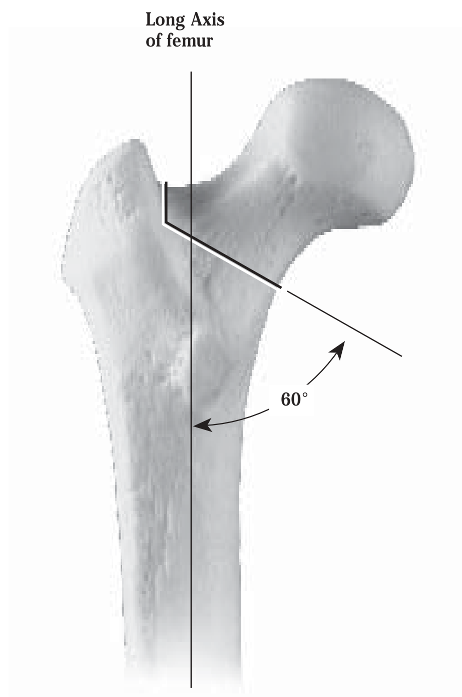


Fig. 3

Preparation of the Femur

After removing osteophytes, particularly anterior osteophytes, use the Box Osteotome or the Trochanteric Reamer to remove the medial portion of the greater trochanter and lateral femoral neck (Fig. 4).

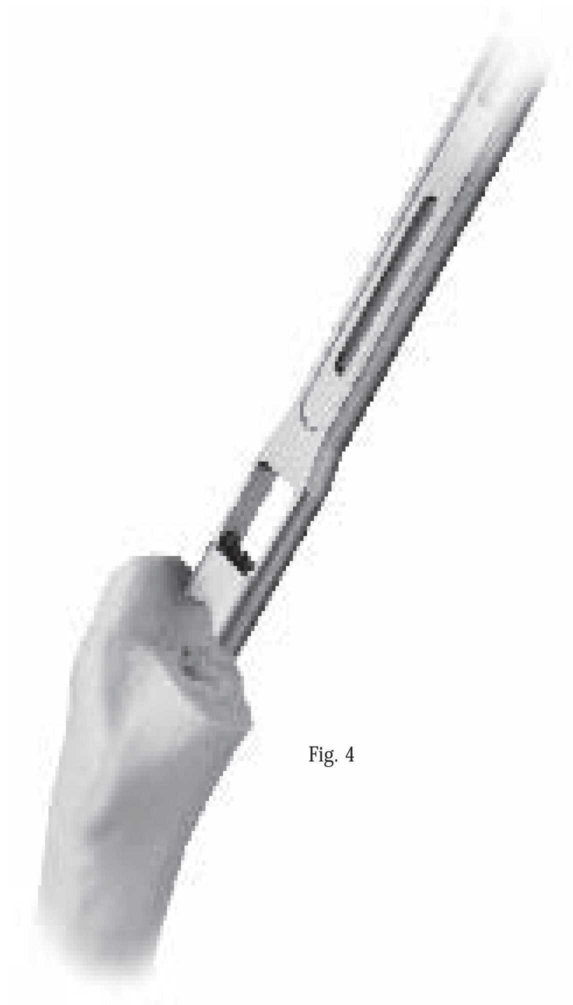
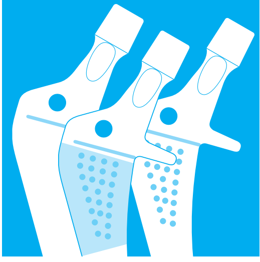


Fig. 4



After removing this cortical bone, insert the Tapered Awl to open the medullary canal (Fig. 5).

The center of the femoral canal can be found by reaming just anterior to the trochanteric fossa. A powered Trochanteric Reamer can be used to ream sufficient lateral greater trochanteric bone so that the rasp can be placed in a neutral varus-valgus alignment (Fig. 6).

Use the *VerSys* System Rasps when preparing the canal for a *VerSys* Cemented implant. Do not use the Large Metaphyseal or Enhanced Taper Rasps when performing a cemented procedure. These rasps are engraved with a "LM" or "ET" near the trunnion for easy identification. Also, do not use the Rasp Alignment Tip in the cemented technique. The threads on the tip of the standard rasp must be visible before rasping the canal (Fig. 7).

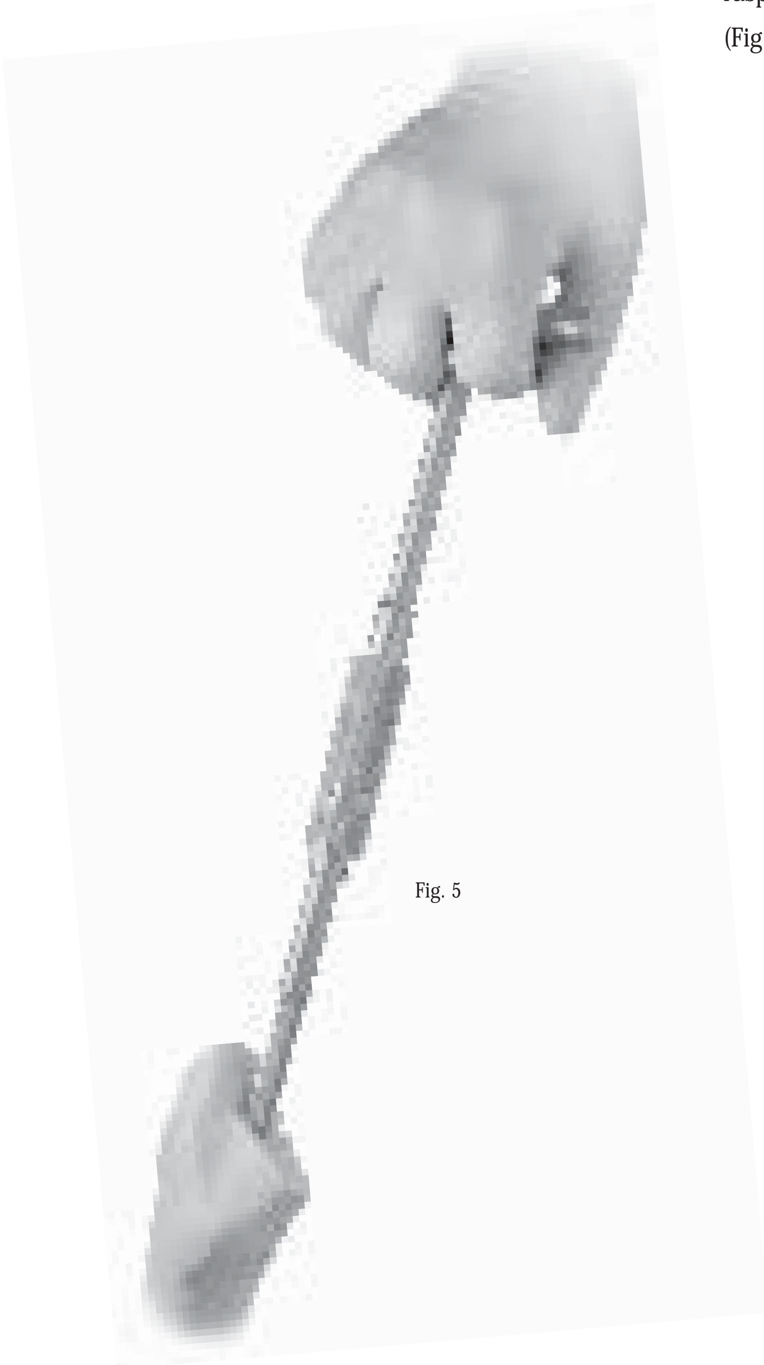
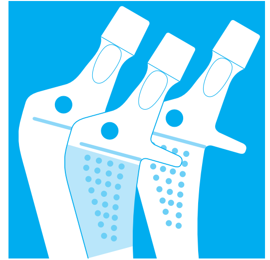


Fig. 5

Fig. 6



It is important to antevert the femoral rasp by approximately 10 to 20 degrees when driving it into the medullary canal. The amount of femoral rasp anteversion is related to the natural anteversion of the patient's femoral neck. Insert the rasp parallel to the cortices of the femoral neck to re-create the patients natural anteversion, except in cases of excessive anteversion.

Start with a rasp 1 - 2 sizes smaller than the size selected during templating. The rasp should advance with each moderate tap of the mallet (Fig. 8). Rasp the femoral canal with sequentially incremental rasp sizes until the cortical envelope is filled. With the *VerSys* Cemented implants, it is necessary to countersink the rasp more than 5mm (5 - 10mm) before having enough room in the medullary canal to go up to the next size. If the rasp countersinks only 2 - 4mm, this will be the final size.

Calcar Planing

Once the final rasp is securely seated, remove the Rasp Handle and leave the rasp in the medullary canal. (It is necessary to countersink the rasp into the bone by 2 - 4mm to adequately prepare the calcar.) The exposed Rasp Trunnion serves as a centering guide for the Calcar Planer. A choice of small and large planers are available to meet the needs of different femoral sizes. Choose the proper size of Planer and mount it on the Rasp Trunnion (Fig. 9). **Start the powered handpiece with the Planer prior to calcar contact to prevent chipping of the medial bone.** One advance of the planer using a fluid motion is sufficient to level the calcar and ensure a precise fit of the collar on the medial calcar region.

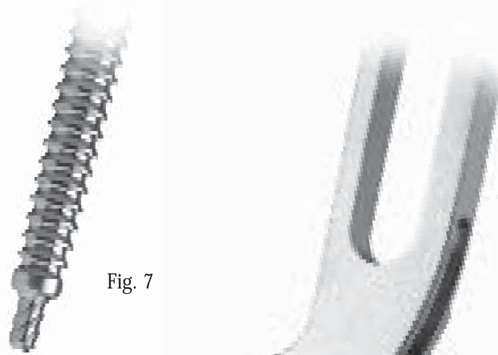


Fig. 7

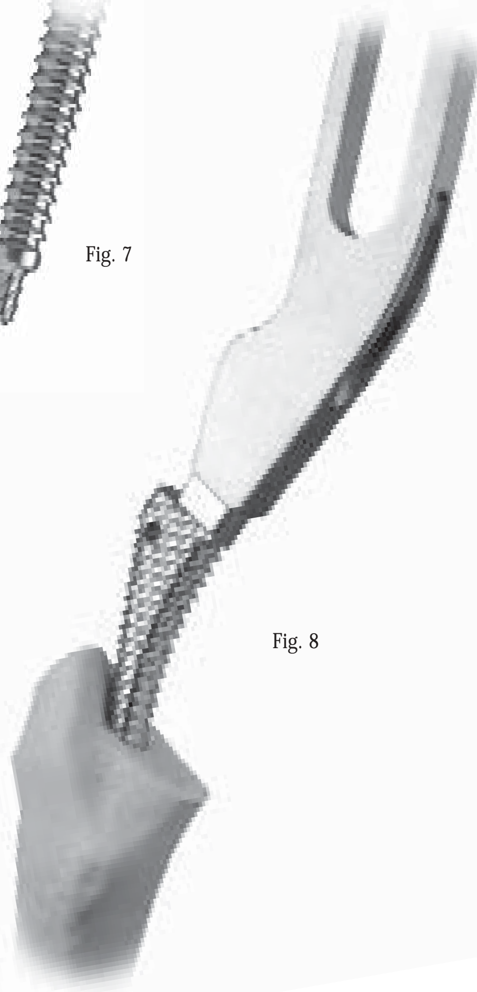


Fig. 8

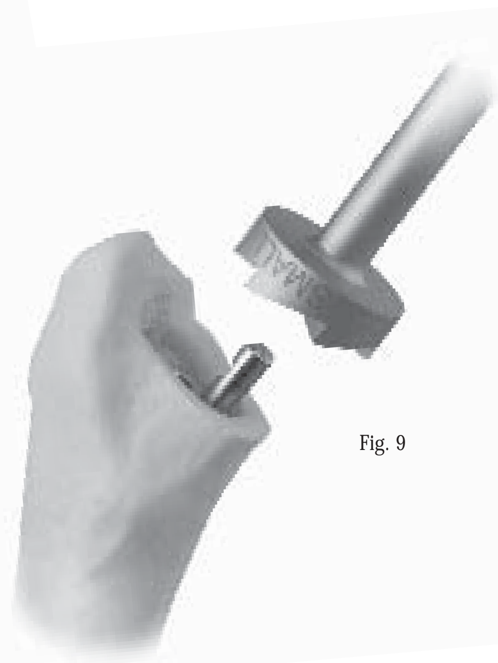
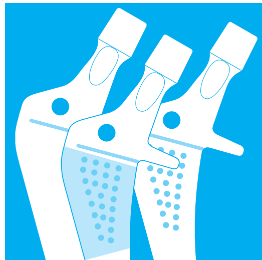


Fig. 9



Trial Reduction

Modular Cone Collar Provisionals affix to the Rasp Trunnion and allow for determination of joint stability, leg length, and range of motion (Fig. 10). The Cone Collar Provisionals replicate the collar/neck geometry of the femoral component for exact trial reductions. The system utilizes one Cone Collar Provisional for two Rasp sizes (e.g. 12/13 is engraved on the Cone Collar Provisional and indicates usage with only the 12mm and 13mm rasps). The standard offset Cone Collar Provisionals are engraved with "CEM" for easy identification. There are also three Cone Collar Provisionals etched with "CEM EXT" designed for the extended offset cemented stems.

If the acetabulum has already been implanted, assemble the Cone Collar Provisional and femoral head on the rasp to perform a trial reduction. Observe the relationship of the center of the femoral head to the top of the greater trochanter with the Cone Collar Provisional to confirm the preoperative plan. Note the sciatic nerve tension and range of motion, and confirm positions of potential instability. Also, confirm whether the preoperative goal for leg length has been achieved.

Note: The *VerSys* Cemented stems are manufactured from forged cobalt chrome. This material has adequate strength to allow cutouts in the A/P dimension in the neck region, which maximizes the range of motion.

Preparation for the *V-Lign*™ Proximal Centralizer (Optional)

After trial reduction, remove the Cone Collar Provisional from the rasp and attach the *V-Lign* Slot Milling Guide to the trunnion of the rasp (Fig. 11).

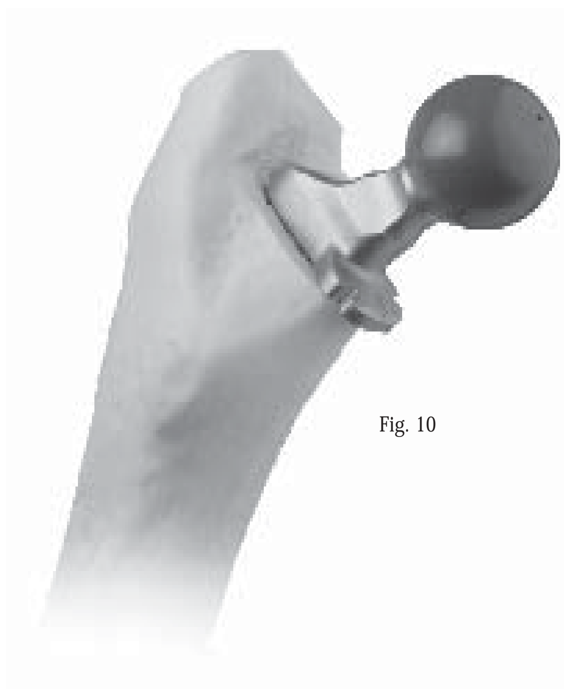


Fig. 10

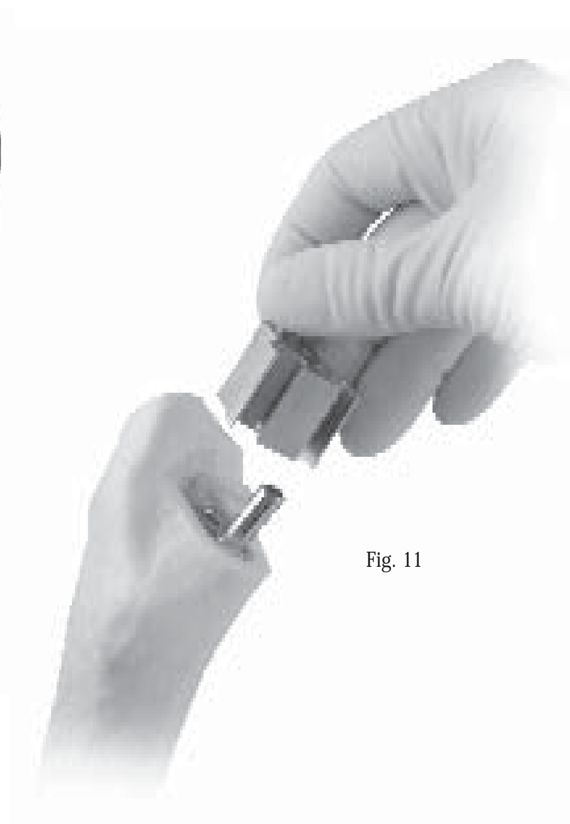


Fig. 11

Lock the guide securely in place with a standard 3.5mm hex-head screwdriver (Fig. 12). The guide contains two milling channels which correspond to the two arms of the *V-Lign* Proximal Centraizer.

Use a *V-Lign* Slot Milling Burr to machine two grooves in the femoral neck. Fit the burr into the *V-Lign* Slot Milling Burr Sleeve and place it into the first slot of the Milling Guide. The ball-shaped protrusion on the burr sleeve must be seated firmly into a corresponding cavity on the Milling Guide while milling. This ensures the accuracy of the location of the milled grooves. Orient the burr tip away from the femur and apply power in drill mode prior to engaging the calcar (Fig. 13). Swing the powered burr only once through the calcar, medial to lateral, in a pendulum-like motion. **Special note: Stop the burr and do not use power when removing the burr and sleeve assembly from the Milling Guide. Excessive milling of the grooves will affect the final fit and accuracy of the *V-Lign* Proximal Centralizer.**

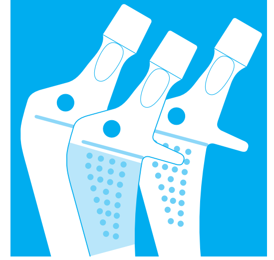
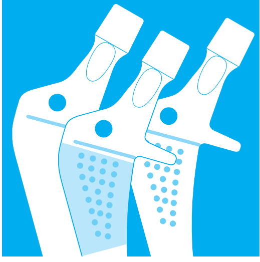


Fig. 12

Fig. 13



Remove the burr and sleeve assembly and insert the *V-Lign* Stabilizer into the first milled slot. The stabilizer has a spherical protrusion that must be seated firmly in a corresponding recess in the guide (Fig. 14). This ensures that the Milling Guide and rasp are stabilized in the canal while the second *V-Lign* groove is milled (Fig. 15).

Remove the Milling Guide from the rasp and use the *V-Lign* Trial Template to ensure that the *V-Lign* grooves are properly aligned (Fig. 16). It is necessary to create two *V-Lign* grooves with adequate length and depth to achieve proper centralization. Absence of two intact grooves or calcar bone deficiencies restricts the use of the *V-lign* centralizer. The Proximal centralization sleeve is used as the primary centralization method if this condition exists.

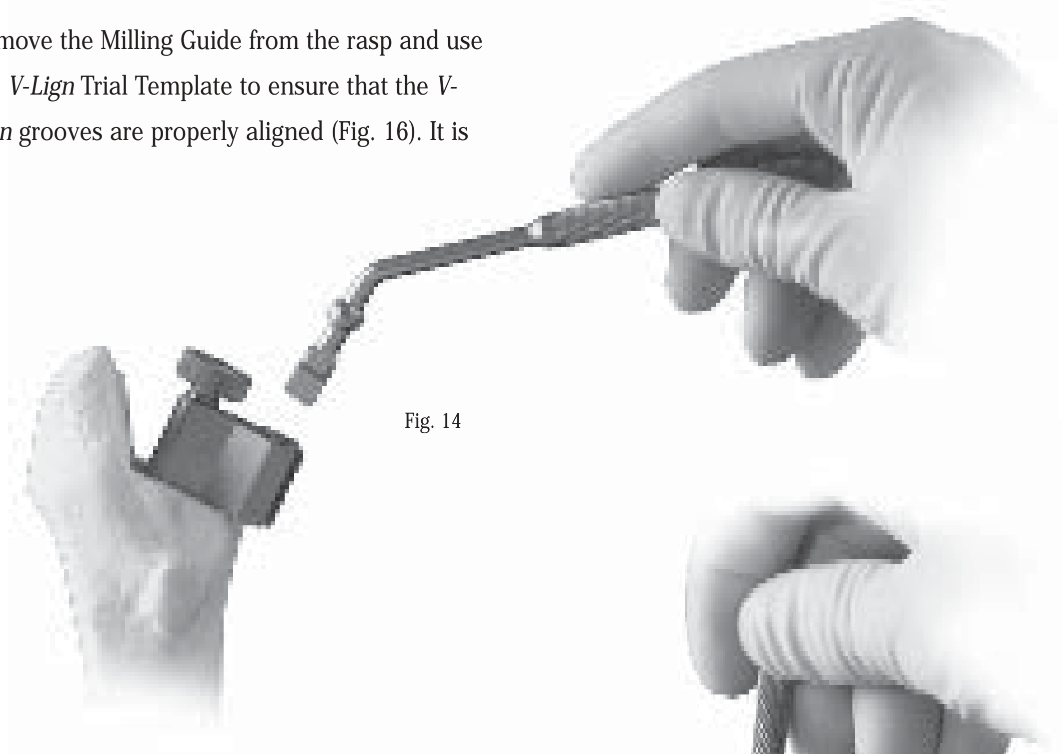


Fig. 14

Fig. 15

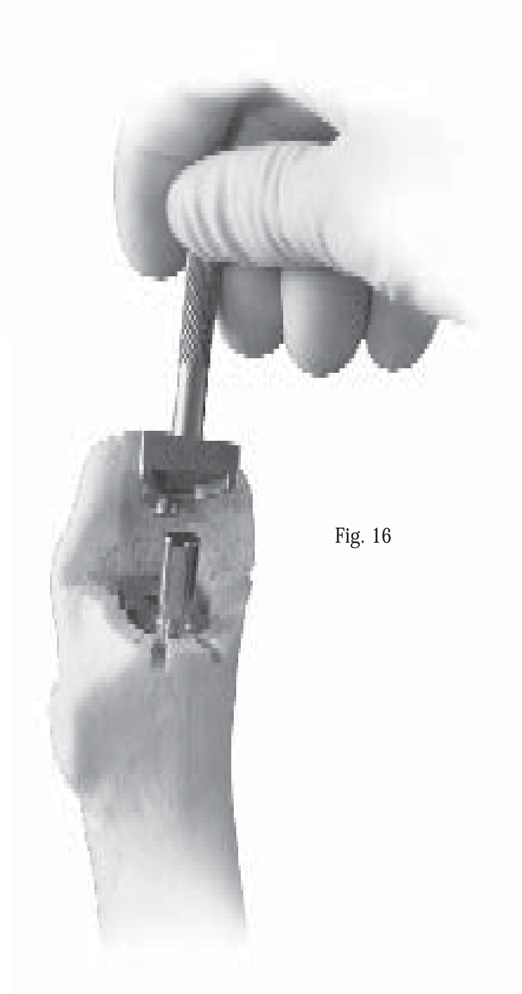
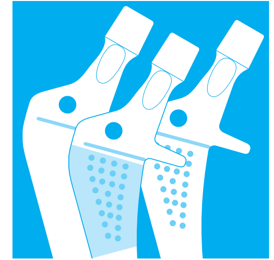


Fig. 16



Mount the final Cone Collar Provisional back on the rasp. Use the engraved marks on the provisional to make visual marks on the calcar bone (Fig. 17). This mark will aid in the alignment of the stem during insertion. Then remove the rasp from the medullary canal. Trim any bone remaining in the grooves with the narrow-nosed Rongeur provided with the instrument set (Fig. 18).

The Femoral Head is then impacted on the 12/14 taper prior to assembly of the Proximal and Distal PMMA Centralizers. Choose the Femoral Head with a neck length that corresponds to the Provisional Femoral Head used during the trial reduction. Check to ensure the taper is dry and clean. The Femoral Head is placed on the taper with a twisting motion until it locks on the taper. One sharp strike using the Femoral Head Impactor and mallet is performed to seat the Femoral Head. Test the security of the head fixation by trying to remove the head by hand. If the head must be removed after impaction, use the mallet and Stem Driver to carefully disengage the head from the taper by striking the lateral side of the head.

Attach the *V-Lign* Proximal Centralizer to the underside of the collar on the stem with the apex of the 'V' and the web connecting the two arms of the centralizer pointing TOWARD the stem. Press the pegs of the Centralizer into the A/P grooves on the collar. Eliminate the gap between the centralizer and the stem by firmly pressing the Centralizer onto the underside of the collar (Fig. 19).

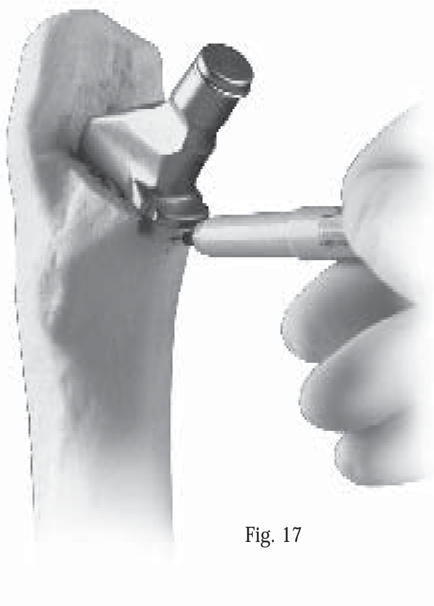


Fig. 17

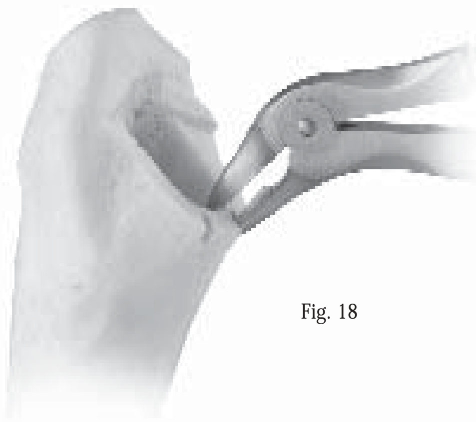


Fig. 18

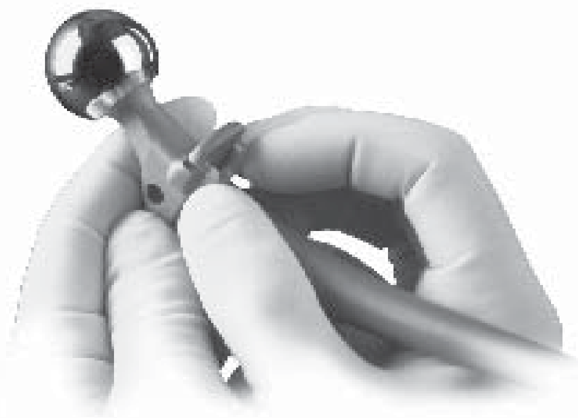
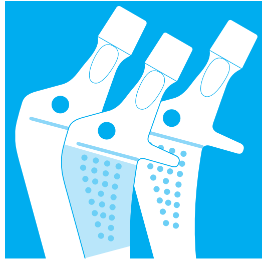


Fig. 19



Preparation for the Proximal Centralization Sleeve (Optional)

The Proximal Centralization Sleeve is another option for proximal centralization of the *VerSys* Cemented stems. The device provides centralization on the medial, anterior, and posterior sides of the implant. The Proximal Centralization Sleeve does not require use of the *V-lign* milling technique. This is the primary mode of proximal centralization for the *VerSys* Cemented CT stems as the minimized collar is insufficient in size to support the *V-Lign* Centralizer. This is an alternate mode of proximal centralization for the *VerSys* Cemented and Cemented Plus stems.

Spread a thin layer of doughy cement on the interior surface of the Proximal Centralization Sleeve. Attach the Sleeve to the stem so that the ribs on the A/P walls of the Sleeve are seated in corresponding grooves on the A/P sides of the stem. The Sleeve must be attached to the stem immediately prior to insertion of the stem into the canal (Figs. 20 & 20a).

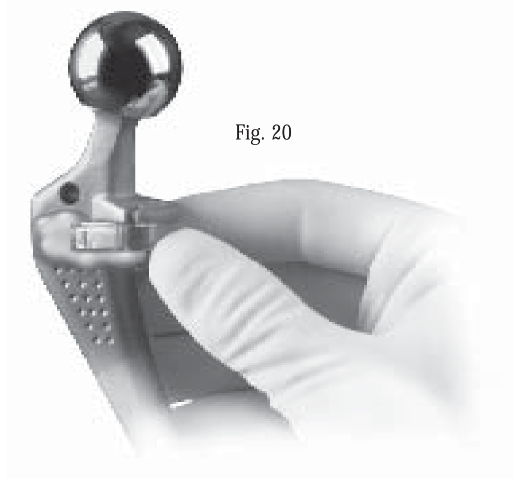


Fig. 20

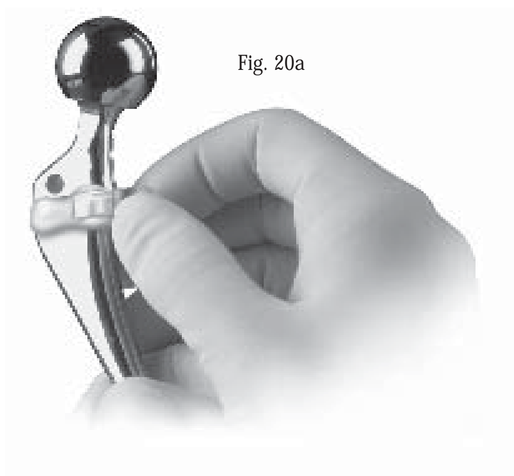


Fig. 20a

Note: Both the *V-Lign* Proximal Centralizer and the Proximal Centralization Sleeve are included in the femoral implant package. EITHER the *V-Lign* Proximal Centralizer OR the Proximal Centralization Sleeve can be used. Simultaneous use of both types of centralizers is NOT recommended.

Sizing and Preparation of the Canal

A Distal Centralizer is recommended for distal stem centralization. The size of the femoral canal at the level of the Distal Centralizer can be accurately assessed using the IM sizers provided in the general instrument case. The Sizers have marks that indicate the depth of the Distal Centralizer measured from the medial calcar for each stem size (Fig. 21).

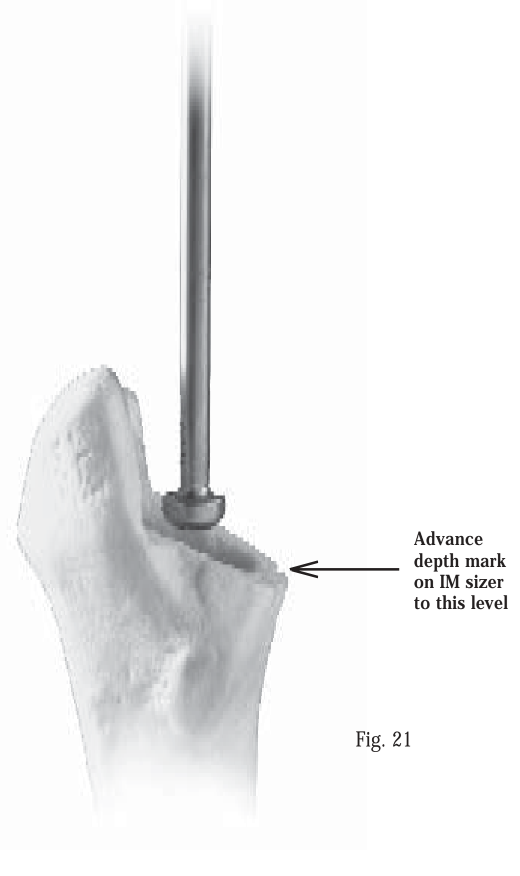


Fig. 21

The largest sizer that fits the canal (at the required depth) is the size of the Distal Centralizer that should be used.

Note: If the canal sizer is tight in the canal, then it is important to choose a distal centralizer one size smaller than the size of the canal sizer. This method of sizing allows the implant and distal centralizer to pass freely in the canal during insertion.

Rasp Size	Approx Size of Canal Created by Rasp*
12	10 mm
13	11 mm
14	12 mm
15	13 mm
16	14 mm
17	15 mm

*This is the approximate size of the canal created by each rasp at the level of the distal centralizer.

Choose a Distal Centralizer of appropriate size. The Distal Centralizer's inner diameter has a taper through its length similar to the head/neck taper. Before attaching the Distal Centralizer to the stem, apply a thin layer of cement to the distal tip or fill the tapered hole in the Centralizer with cement. This will help promote a good bond between the stem and Distal Centralizer.

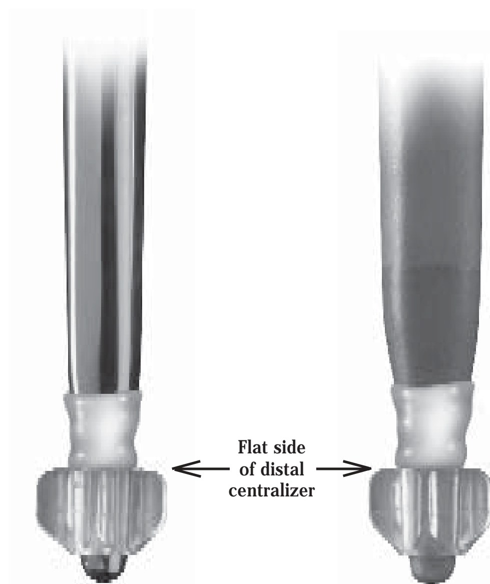
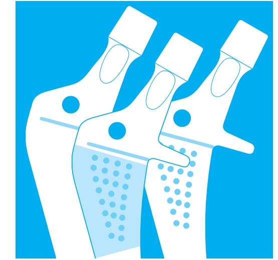


Fig. 22 Fig. 22a



When attaching the Centralizer, the flat side of the Centralizer is directed toward the stem tip. The tip should be introduced through the opening on the flat side of the centralizer (Fig. 22 and 22a).

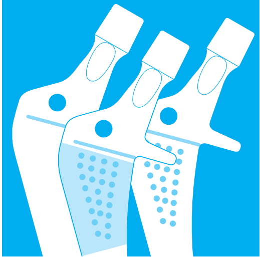
The centralizer is advanced on the stem tip with a minimum force until it comes to rest in its final position. **The centralizer does not need to be twisted or forced on the stem.**

Prepare the canal with pulsatile lavage irrigation and dry it thoroughly. Place a distal cement restrictor at a depth to allow for 2cm of cement beyond the tip of the prosthesis.

The IM Sizers can be used to size for the cement restrictor. The depth calibrations on the sizers are in 5mm increments. Therefore, the sizers which can be passed to 4 calibrations (2cm) beyond the corresponding stem calibration is the size of the cement plug.

Stem Size	Stem Length*	Depth to which Cement Plug should be Inserted*
12	125mm	145mm
13	130mm	150mm
14	135mm	155mm
15	140mm	160mm
16	145mm	165mm
17	150mm	170mm

*All measurements are from the medial calcar.



Cement Introduction and Stem Insertion

Introduce porosity reduced cement into the femoral canal in a retrograde manner, distal to proximal (Fig. 23), and follow with adequate pressurization. Then insert a prosthesis of the same size as the final rasp with the appropriate Proximal and Distal Centralizers into the femoral canal. During insertion, the stem axis should be parallel to the longitudinal axis of the femur. Moderate resistance confirms good pressurization.

When implanting a stem using the *V-Lign* Proximal Centralizer, stop inserting the stem with the collar approximately 1cm from the calcar (Fig. 24). Clean excess cement in the region of the medial calcar for improved visualization and make final rotational micro-adjustments to ensure that the arms of the *V-Lign* Proximal Centralizer are nested in the corresponding grooves in the calcar. Use the reference mark made earlier to guide the *V-Lign* Centralizer into the milled channels. The center mark on the collar of the implant corresponds with the mark on the Cone Collar Provisional.

Remove all residual cement. Be sure to achieve complete calcar contact for effective load

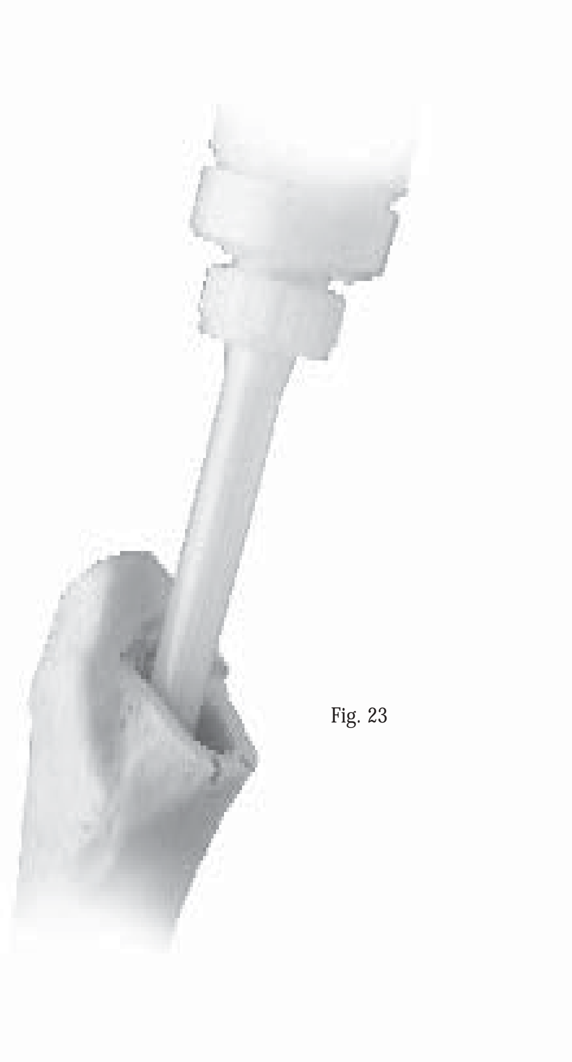


Fig. 23

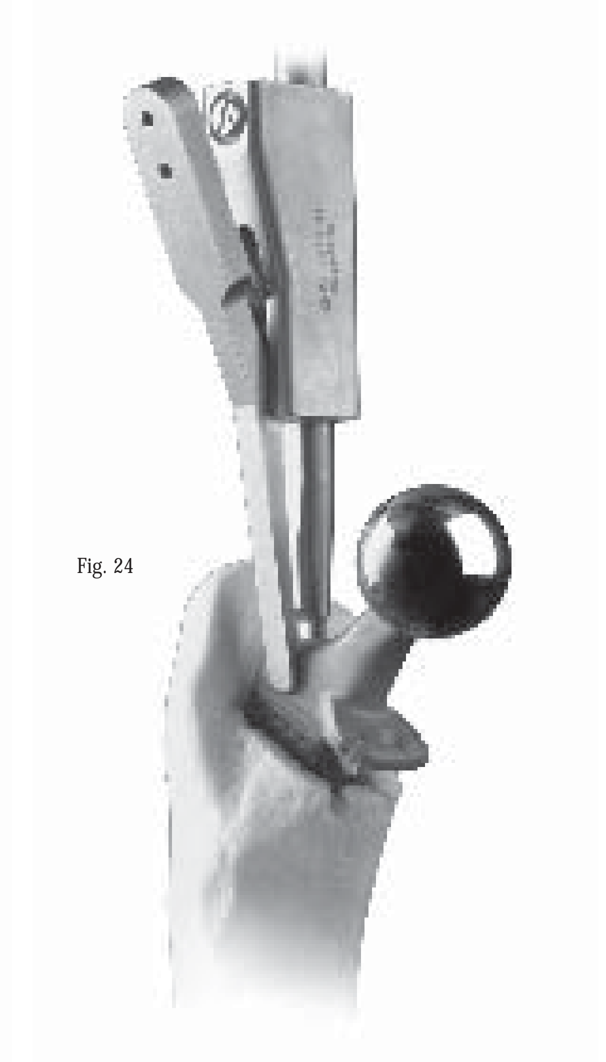


Fig. 24

transfer to the femur. After final seating of the prosthesis, perform a visual inspection to ensure proper proximal centralization is attained. Apply the Burke Fixation Clamp to hold the prosthesis in place while the cement is polymerizing. (Use of the Burke Fixation Clamp is recommended only when the *V-Lign* Proximal Centralizer is used.)

To affix the Burke Clamp, place the ball of the Clamp on the dimple on the collar of the prosthesis and straddle the other prong to the lateral cortex of the femur (Fig. 25). Tighten the Clamp and leave it attached until the cement is completely polymerized.

When inserting a *VerSys* CT stem, the implant is prepared with the femoral head assembled on the 12/14 taper and the centralizers attached to the implant. The proximal centralizer sleeve is the chosen method when utilizing a *VerSys* CT stem. The implant is inserted with the stem axis parallel to the longitudinal axis of the femur.

Moderate resistance confirms good pressurization. Stop inserting the implant when the line adjacent to the minimized collar on the implant matches the surgical osteotomy line. Be careful not to countersink the implant during insertion as the minimized collar provides little resistance during the final stage of insertion.

Note: Impacting the stem driver while inserting the implant with an assembled head may cause the femoral head to loosen. Test the security of the head fixation by trying to remove the head by hand once the implant is seated. One sharp strike using the femoral head impactor and mallet should be used to ensure the femoral head is seated on the taper.

Reduce the hip joint and assess the leg length, range of motion, stability, and abductor tension one final time. After obtaining hemostasis, insert a *Hemovac*® Wound Drainage device and close the wound in layers.

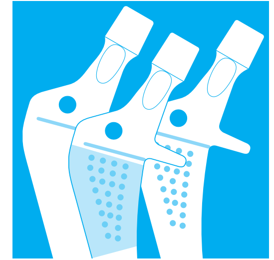
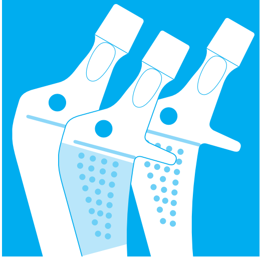


Fig. 25



NOTES:

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