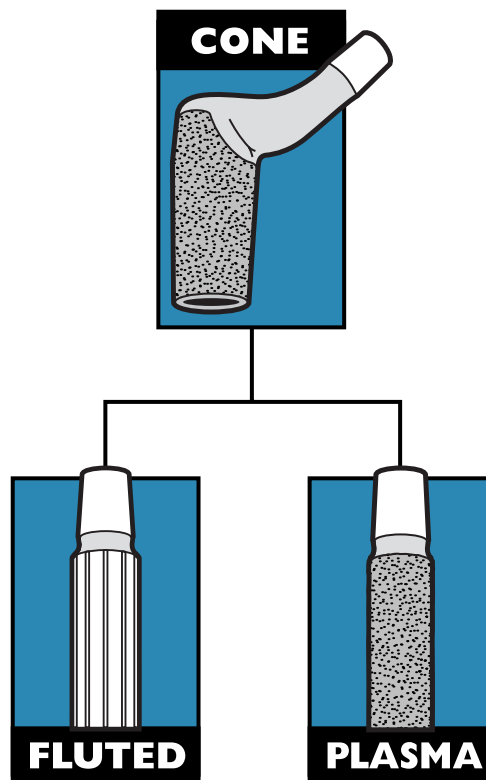
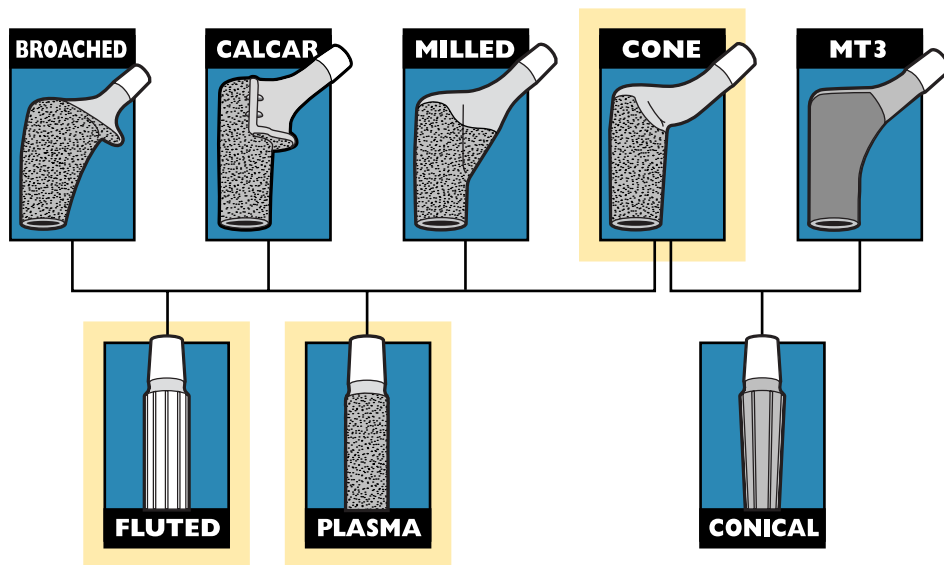


Restoration® Modular Revision Hip System Surgical Protocol



Restoration® Modular
Cone Body/Fluted & Plasma Distal Stem
Femoral Components
Using the Restoration® Modular
Instrument System



**Restoration® Modular
Revision Hip System**

Restoration® Modular Revision Hip System Surgical Protocol

Restoration® Modular Cone Body/Fluted & Plasma Distal Stem Femoral Components Using the Restoration® Modular Instrument System

Indications

The Restoration® Modular Hip System is intended for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur. The indication for use of total hip replacement prostheses include:

- Rheumatoid arthritis.
- Correction of functional deformity.
- Revision procedures where other treatments or devices have failed.
- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Contraindications

- Overt infection.
- Skeletally immature patients.
- Distant foci of infections, which may cause hematogenous spread to the implant site.
- Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram.
- Cases where there is a loss of abductor musculature, poor bone stock, or poor skin coverage around the hip joint, which would make the procedure unjustifiable.

Conditions Presenting Increased Risk Of Failure Include But Are Not Limited To:

- Uncooperative patient or patient with neurologic disorders, incapable of following instructions.
- Osteoporosis.
- Metabolic disorders which may impair bone formation.
- Osteomalacia.
- Excessive loads due to patient activity and/or patient weight.

Patients should be warned of these contraindications.

Acetabular Options

Stryker® Orthopaedics offers a wide variety of acetabular components that are compatible with the Restoration® Modular Femoral Components. The surgeon should refer to a specific acetabular component's surgical technique for a discussion of acetabular surgical procedures. The Restoration® Modular Hip System is compatible only with Stryker® Orthopaedics V40™ femoral bearing heads.

Restoration® Modular Surgical Protocol

System Overview

The Modular Cone Body/Fluted Distal Stem & Plasma Distal Stem Femoral components are part of the Restoration® Modular Revision Hip System. The system takes advantage of the long clinical experience with distally fixed implants, while making use of modern technology to enhance proximal load transfer to the femur. This is achieved by mating a selected proximal body with a selected distal stem to provide a femoral prosthesis that minimizes proximal-distal mismatching, often associated with monolithic implants.

Revision hip surgery is very complex in that the surgeon may face compromised soft tissues, retained cement, severe bone loss, and poor residual bone. A set of implant options is essential to best fit the implant to the present bone defect. The Restoration® Modular Cone Body/Fluted Distal Stem & Plasma Distal Stem Femoral components were designed specifically for use in revision cases in which the femoral bone stock is severely compromised in the proximal third or proximal half of the femur. They also may be used for less challenging reconstructive surgery ranging from difficult primary up to, and including, Type III revision cases.[†]

The titanium alloy (Ti-6Al-4V ELI) Cone Bodies are circumferentially plasma sprayed with commercially pure titanium and then over-sprayed with PureFix™ HA. These surface enhancements have demonstrated biocompatibility through many years of use at Stryker® Orthopaedics. Proximally, the Cone Body segment helps maintain rotational and axial stability when adjacent to viable bone. Seven Cone Body diameters are available (range 19mm through 31mm in 2mm increments) with four vertical offsets: +0mm (STD), +10mm, +20mm, and +30mm. These vertical offsets may be used to adjust overall stem length intraoperatively. (See Sizing Charts on page 3.)

The Cone Bodies accept CoCr V40™ Femoral Heads with diameters in 22mm, 26mm, 28mm, 32mm, and 36mm or Alumina Ceramic V40™ Femoral Heads with diameters in 28mm, 32mm, and 36mm.

Note: Do not use the +16mm Femoral Head with any Restoration® Modular Hip combinations.

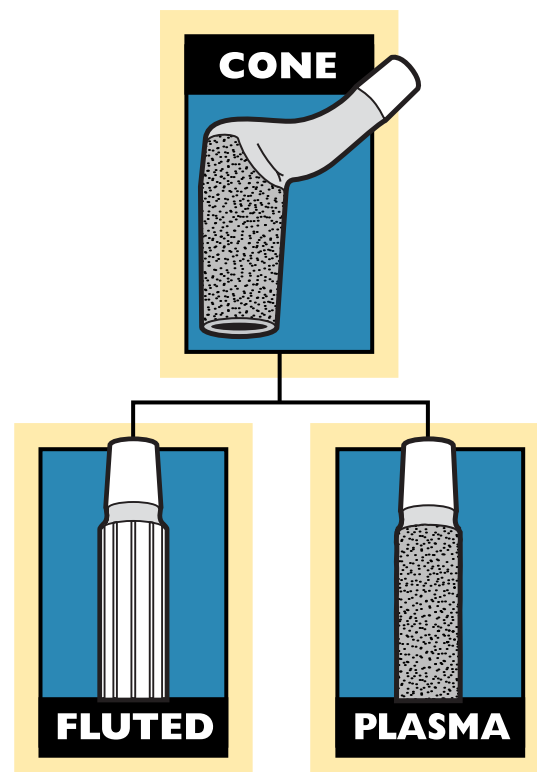
The Fluted Distal Stem design provides diaphyseal rotational stability through nine sharp, polished flutes on each stem. A tri-slot is featured on the distal end of all (13mm and larger) 167mm and longer stems. The stem diameter is measured on the outside of the flutes. Each flute is 1mm high, the outside of which determines the major diameter. The inside of the flutes determines the minor diameter, (e.g., a 16mm [major] diameter stem has a 14mm minor diameter – between the flutes).

The Plasma Distal Stem design provides diaphyseal rotational and axial stability. The Plasma Distal Stems are also circumferentially plasma sprayed with commercially pure titanium and then over-sprayed with PureFix™ HA. The bowed Plasma stems (167mm, 217mm, 267mm, 317mm) are available as a fully-coated or tri-slot option (tri-slot in 13mm - 26mm diameters). The diameters of these distal stems are measured at the mid-way point of the peak of the plasma coating.

Both the Fluted and the Plasma stem designs are available in five lengths – 127mm, 167mm, 217mm, 267mm, and 317mm. Each Fluted & Plasma Distal Stem length comes in 16 diameters from 11mm to 26mm in 1mm increments. The 127mm and 167mm Fluted & Plasma Distal Stems are offered with a straight design option. The 167mm Fluted & Plasma Distal Stem is also offered with a bowed option. The 217mm, 267mm, and 317mm Fluted & Plasma Stems are only offered with a bowed option.

The total length of the Cone Body/Fluted Distal Stem & Plasma Distal Stem construct will be dependent upon the body and stem chosen. Standard stem lengths are measured from the +0mm (STD) Cone Body with a +0mm (STD) Femoral Head from the head center to the distal tip of each of the five lengths of Fluted or Plasma Distal Stems. Review Sizing Charts on page 3 for stem lengths.

Note: The Cone Body/Fluted & Plasma Distal Stem lengths are measured from the +0mm (STD) Cone Body with a +0mm (STD) Femoral Head from the head center to the distal tip of the Fluted Distal Stem or Plasma Distal Stem.



[†] D'Antonio, J., et al. Classification of Femoral Abnormalities in Total Hip Arthroplasty. *Clin Ortho and Rel Research*. 1993; Number 296: pp. 133 – 139. Longjohn, D. & Dorr, L. Bone Stock Loss and Allografting: Femur. *Revision Total Hip Arthroplasty*. 1999. pp. 100 – 111.

Stem Length Options

Cone Body Sizes and Head Offsets with V40™ Femoral Heads available in 22mm, 26mm, 28mm, 32mm, & 36mm

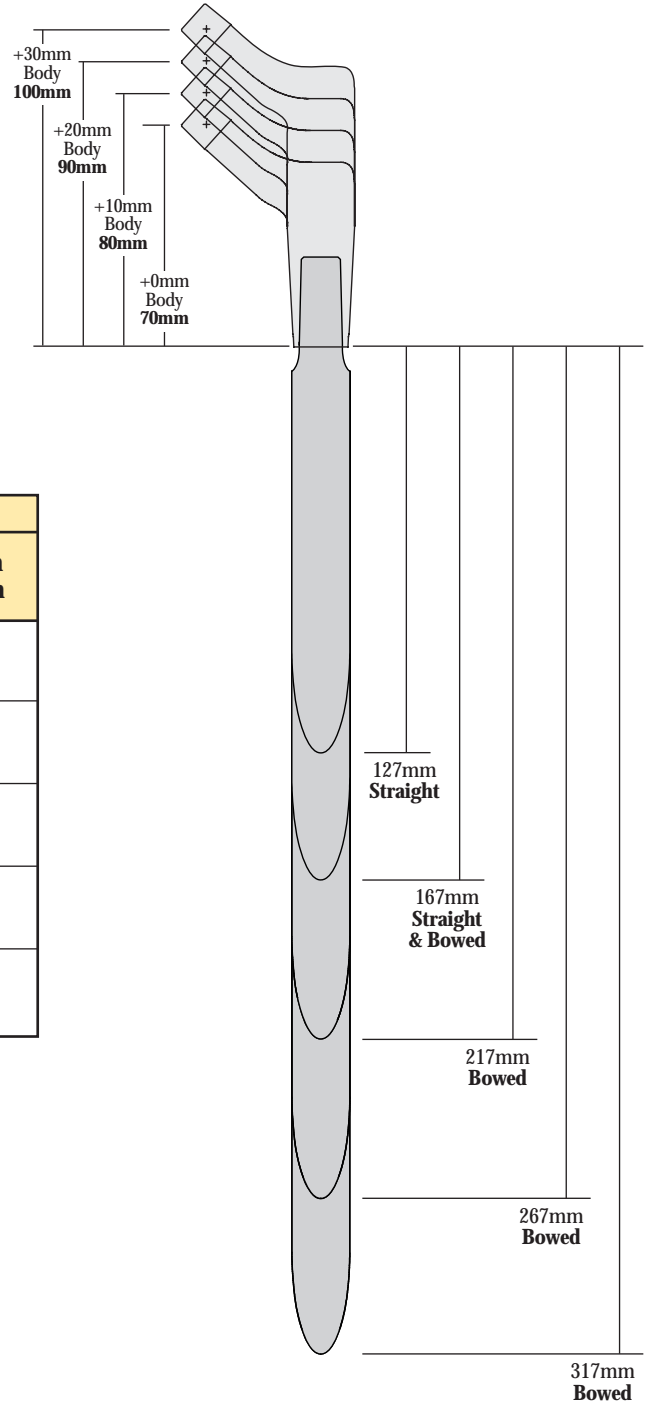
IMPORTANT: Do not use the +16mm Femoral Head with any Restoration® Modular Hip combination.

Cone Body Sizes	-4mm*	+0mm (STD)	+4mm	+8mm	+12mm
19mm	31mm	34mm	37mm	40mm	43mm
21mm	33mm	36mm	39mm	42mm	45mm
23mm	37mm	40mm	43mm	46mm	49mm
25mm	41mm	44mm	47mm	50mm	53mm
27mm	41mm	44mm	47mm	50mm	53mm
29mm	41mm	44mm	47mm	50mm	53mm
31mm	41mm	44mm	47mm	50mm	53mm

*Not available in 22mm or 26mm diameter head (see Head Compatibility chart on pages 17 or 22).

Cone Body/Fluted Distal Stem & Plasma Distal Stem Sizes

Cone Body Sizes	Neck Angle	Distal Stem Lengths (mm)	Distal Stem Diameters
19mm 21mm 23mm 25mm 27mm 29mm 31mm	132°	127, 167, 217, 267, 317	11mm – 26mm in 1mm Increments



Cone Body/Fluted Distal Stem & Plasma Distal Stem Combined Overall Lengths**

Fluted Distal Stem & Plasma Distal Stem Sizes	Cone Body Heights			
	70mm +0mm (STD)	80mm +10mm	90mm +20mm	100mm +30mm
127mm Length 11mm-26mm dia. (Straight)	197mm	207mm	217mm	227mm
167mm Length 11mm-26mm dia. (Straight & Bowed)	237mm	247mm	257mm	267mm
217mm Length 11mm-26mm dia. (Bowed)	287mm	297mm	307mm	317mm
267mm Length 11mm-26mm dia. (Bowed)	337mm	347mm	357mm	367mm
317mm Length 11mm-26mm dia. (Bowed)	387mm	397mm	407mm	417mm

**Femoral head neck length options will increase overall stem lengths – range -4mm, +0mm (STD), +4mm, +8mm, and +12mm. Head center (+0mm STD) to distal stem tip.

Alumina Ceramic Head Compatibility

Size	Offsets Available
28mm	-2.7mm, +0mm (STD), +4mm
32mm	-4mm, +0mm (STD), +4mm
36mm	-5mm, +0mm (STD), +5mm

Restoration® Modular Surgical Protocol

Bone Defect Classifications

Type 1 - Minor Bone Loss

- The metaphysis is expanded, but intact.
- The calcar is partially absent.
- There is minimal bone loss anteriorly and posteriorly.
- The diaphysis is intact.

Type 2 - Significant Bone Loss

- The metaphysis is compromised.
- There is no calcar.
- There is minimal bone loss anteriorly and posteriorly.
- The available proximal bone may be thin, sclerotic, and incapable of support.
- The diaphysis is intact.

Type 2A - The calcar is non-supportive, but the diaphysis is still intact.

Type 2B - The calcar is non-supportive, the anterolateral metaphysis is deficient, but the diaphysis is still intact.

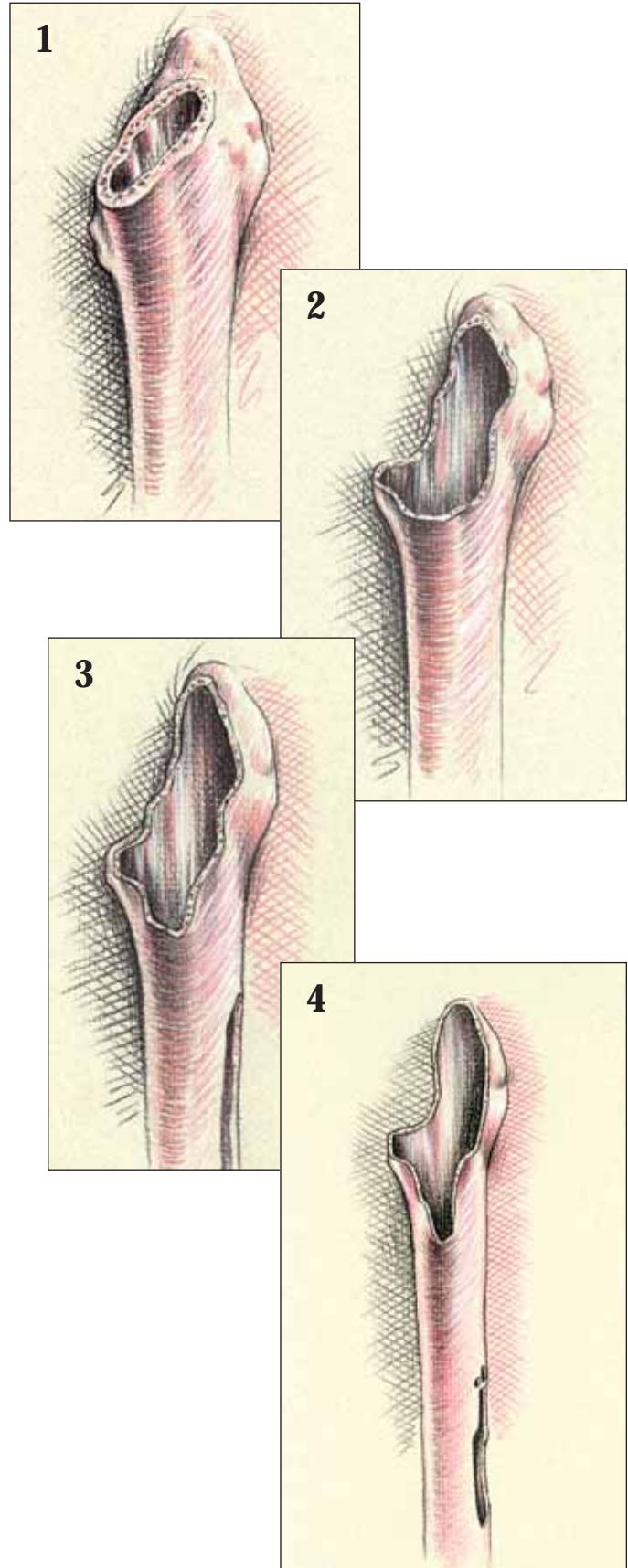
Type 2C - The calcar is non-supportive and the posteromedial part of the metaphysis is deficient, but the diaphysis is still intact.

Type 3 - Massive Bone Loss

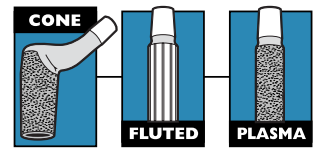
- Complete circumferential bone loss in the metaphysis, extending to the diaphysis.
- The metaphysis and part of the diaphysis are deficient.
- The anterolateral bone and supporting subtrochanteric metaphyseal bone are absent.
- The metaphysis is not stable and will not offer rotational stability.
- There is massive bone loss anteriorly and posteriorly.
- The stability of the implant is dependent on distal diaphyseal fixation.

Type 4 - Massive Bone Loss

- Extensive circumferential segmental bone loss proximally.
- Extensive cavitory loss involving the entire diaphysis.
- Extensive ectasia of the diaphysis.
- Proximal femoral allograft required with reduction osteotomy of the diaphysis.
- Cortical diaphyseal bone is often thin and needs to be supplemented with cortical strut grafts.
- Segmental defects can be repaired with cortical strut graft and cerclage wiring, and cavitory defects can be filled with impacted particulate graft.



Source: D'Antonio, J., et al. Classification of Femoral Abnormalities in Total Hip Arthroplasty. *Clin Ortho and Rel Research*. 1993; Number 296: pp. 133 – 139.
Longjohn, D. & Dorr, L. Bone Stock Loss and Allografting: Femur. *Revision Total Hip Arthroplasty*. 1999. pp. 100 – 111.



Preoperative Evaluation and Planning

The Restoration® Modular Cone Body/Fluted & Plasma Distal Stem Femoral Hip System offers a complete set of femoral X-ray templates for the surgeon to help assess the implant requirements. All seven Cone Body Templates (with four vertical offsets each) can be combined with each of the Fluted & Plasma Distal Stem Templates. All templates are at 120% magnification. The use of mag markers will facilitate accurate magnification measurements. If mag markers are not used, measure the existing implants on the X-ray to ensure that magnification is approximately 120%.

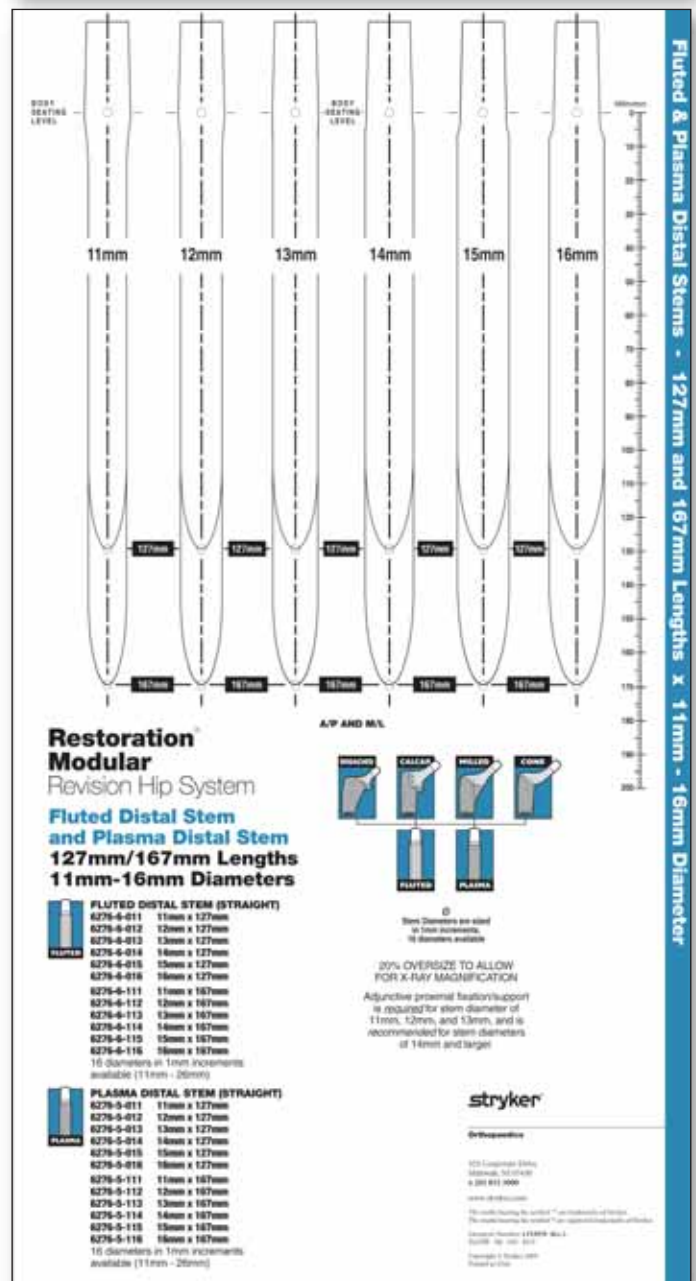
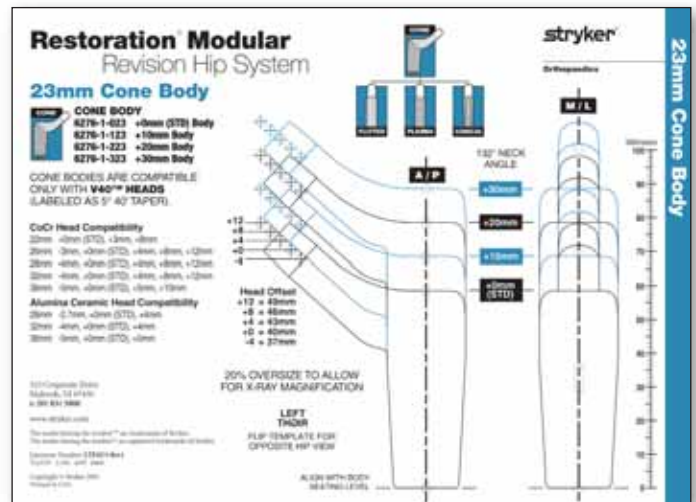
Preoperative planning is strongly recommended for leg length planning, measuring the length of the existing prosthesis being revised, predicting the potential use and type of trochanteric osteotomy, the Cone Body size and vertical offset, and the Fluted & Plasma Distal Stem diameter and length of the prosthesis to be implanted.

Anterior-Posterior (A/P) and Medial-Lateral (M/L) radiographs are necessary for X-ray templating. In cases of severe femoral compromise, a full A/P pelvic X-ray of the operative side as well as the contralateral side is helpful to assess the biomechanical requirements of the reconstruction. The lateral X-ray is informative in that it will show the anterior bow of the femur, which is useful when templating with the 127mm and 167mm straight stems, and the 167mm, 217mm, 267mm, and 317mm, bowed long stems.

First, position an acetabular template over the A/P radiograph, aligning the acetabular shell surface with the subchondral bone. Mark the center of rotation of the acetabulum indicated on the template.

Place the appropriate two-piece femoral template on the radiograph. Ensure that the distal length of the prosthesis will be sufficiently anchored in good cortical bone – this is generally two-to-three canal diameters below the tip of the existing implant or defect. The necessary proximal body height is selected to anatomically correct the leg length.

IMPORTANT: Adjunctive proximal fixation/support is *required* for stem diameters of 11mm, 12mm, and 13mm, and is *recommended* for stem diameters of 14mm and larger.



Restoration® Modular Surgical Protocol

Patient Selection

Proper implant selection is critical to the stability and longevity of the femoral stem implant in hip arthroplasty. Proper implant selection must consider design, fixation, and environmental variables including: patient weight, age, bone quality and size, activity level and preoperative level of health, as well as the surgeon's experience and familiarity with the implant device. Longevity and stability of the implant may be affected by these factors. Surgeons should advise patients of these factors.

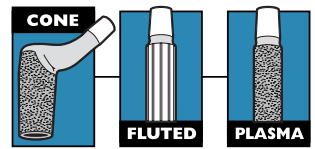
The smaller sized femoral stem implants are intended for use in patients with smaller intramedullary femoral canals. Their geometry has been reduced to accommodate the anatomy of the smaller intramedullary femoral canal, which thereby decreases their fatigue-strength and load-bearing characteristics. Therefore, patients with high physical activity levels, poor bone quality, or who are overweight may be poor candidates for the smaller femoral implant stem.

Patients with high-activity level and/or higher weight patients are at greater risk for implant complications or failures. For patients with poor proximal bone quality, the use of supplemental adjunctive proximal fixation/support is advised for implant stability.

The surgeon must evaluate each situation carefully based upon the patient's clinical presentation before making any decisions regarding the selection of the implant.



A full range of implant sizes provides choice in selecting an implant to meet the specific demands of each patient.



Determine the Approximate Implant Size

Note that the tip of the greater trochanter is approximately at the same level as the center of rotation of the femoral head. If no change in leg length is necessary, then the Cone Body and femoral head center that is closest to the center of rotation marks the appropriate neck length, and femoral head offset required. If leg lengthening is required, choose the Cone Body vertical offset height, neck length and offset that places the center of the femoral head on the overlay above the center of rotation. If it is necessary to shorten the length of the femoral neck, then select the femoral head center below the center of rotation.

Once the proximal geometry has been determined, select the appropriate Fluted or Plasma Distal Stem diameter of the implant by establishing the region of the femoral cortices that appears to be perfectly defined or free from defects which will allow the implant to achieve 10cm - 12cm of suitable distal fixation. Determine also the length required to place the distal stem tip two-to-three canal diameters below the lowest distal defect.

IMPORTANT: Do not plan to use the +30mm Cone Body or the +12mm Femoral Head preoperatively. Use the next larger diameter Fluted or Plasma Distal Stem in the same implant length so that additional vertical offset, neck length, and femoral head offset options are available for adjusting leg length intraoperatively.

IMPORTANT: Do not use the +16mm Femoral Head with any Restoration® Modular Hip combination.

Patient Positioning and Surgical Approach

Revision total hip surgery presents challenges not seen in primary surgery. Therefore, each surgeon should position the patient and use the surgical approach for revision total hip arthroplasty with which he is most familiar. Patient positioning, prepping and draping, the skin incision, soft tissue dissection, and hip dislocation are performed according to the surgeon's preferred technique, making certain to adequately expose the acetabulum and femur as required by each revision situation.

There are also many femoral and trochanteric osteotomy techniques available to surgeons that assist in implant removal, overall reconstruction, and finally, postoperative management. The surgeon should use osteotomies that he is most familiar with and that best fit the challenge faced by each particular revision situation.

Note: To reduce the potential for femoral fracture, it is recommended that areas of defects in the femur are prophylactically cabled prior to reaming and stem insertion. Dall-Miles™ Cables work well to assist the surgeon in this step.



Restoration® Modular Surgical Protocol

Cement Removal

Implant removal and subsequent cement removal can be a challenging proposition. Surgeons should utilize methods they are most familiar with or are most appropriate for the many revision situations that may arise. The Gray™ Revision Instruments are helpful in removing the existing acetabular and femoral prostheses as well as bone cement if present.

After removal of the femoral component, the acetabular component is removed and the acetabulum is prepared. Cement and fibrous tissue still present in the femoral canal may be left to help minimize blood loss during acetabular preparation. After the acetabulum has been prepared, any remaining cement, fibrous tissue, or debris in the femoral canal may be removed and reaming begun.



Gray™ Revision Instruments

Neck Resection Guide – Primary Surgery

A Neck Resection Guide is available for those instances where a surgeon chooses to utilize the Cone Body and Fluted & Plasma Distal Stem implants in a primary surgery, or to excise additional bone in a revision scenario (**Figure 1**).

The resection level should be identical to the level chosen during preoperative templating. Key features of the Neck Resection Guide (**Figure 2**):

1. The slotted area in the proximal portion of the guide helps to reference the proximal tip of the greater trochanter. This is a good landmark that generally coincides with the center of rotation for the femoral head. Align the Cone Body size and its corresponding engraved line with the tip of the trochanter. The notches on the medial extension of the guide correspond with the head centers of the noted diameters.
2. The angled surface provides a plane for marking the level of the cut, or it can be used as a cutting surface for the saw blade. The neck resection is made on the lower angled surface.
3. The long tail of the guide is used for alignment with the femoral shaft axis. It is designed to be inserted under the soft tissues of the posterior aspect of the femur.

Figure 1

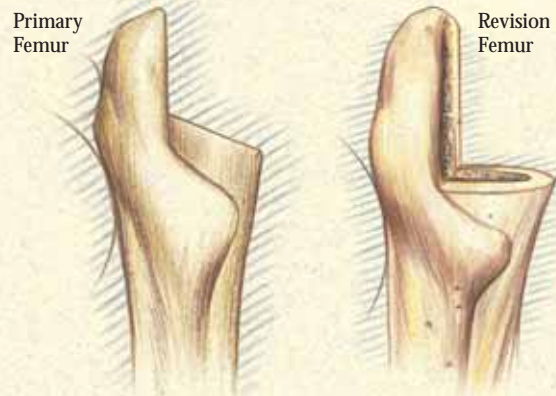
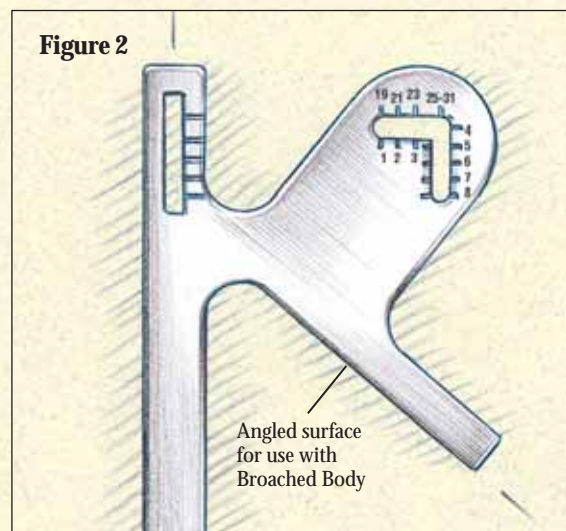
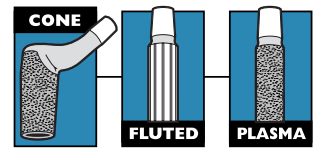


Figure 2





Box Chisel and Starter Awl – Primary Surgery

The Box Chisel may be used to open the proximal femur prior to use of the Starter Awl or in conjunction with the Starter Awl.

Box Chisel Use Prior to the Starter Awl

After the osteotomy has been performed, the Box Chisel is introduced into the anatomic axis of the femoral shaft (**Figure 3**). This will remove a wedge of bone at the medial base of the greater trochanter, helping to achieve neutral/lateral alignment of the Starter Awl.

Use of the Starter Awl and Depth Markings

The Starter Awl can be used by hand or on power. It is designed to open the femoral canal to a diameter of 9.5mm. Assemble the T-Handle or Power Reamer to the proximal end of the awl and target the piriformis fossa to open the canal. The awl is very sharp; therefore, care must be taken to centralize the awl within the femoral canal before reaming is started, avoiding extra osseous penetration with the tip (**Figure 4**).

There are two bold depth marking grooves on the Starter Awl (200mm and 240mm), and markings for the +10mm, +20mm, and +30mm resection levels. Measurement for depth insertion of the Starter Awl when used with all Cone Body/Fluted & Plasma Distal Stems is at the tip of the greater trochanter.

Figure 3

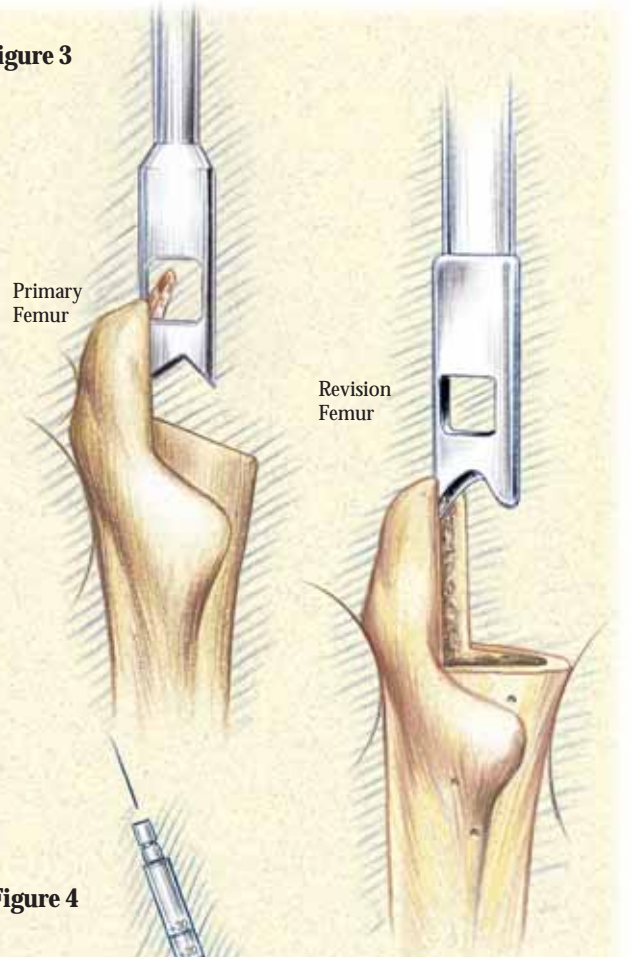
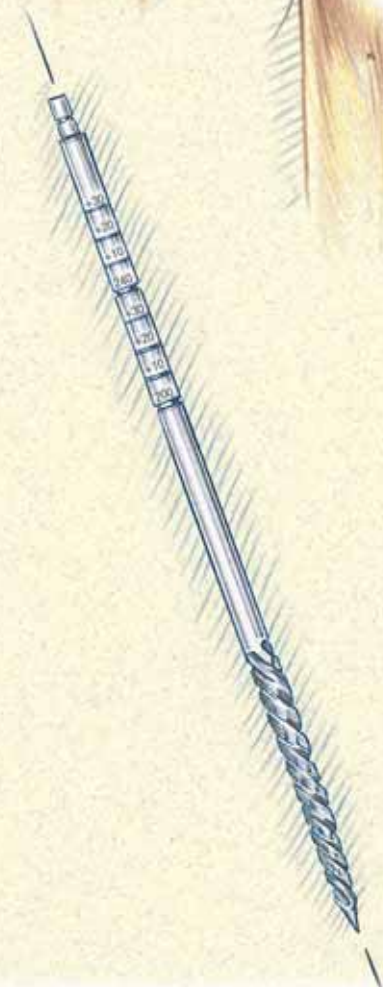


Figure 4



Restoration® Modular Surgical Protocol

Box Chisel and Starter Awl – Primary Surgery (continued)

Box Chisel Use With the Starter Awl

After the awl has been used to open the femoral canal, the T-Handle or Power Reamer is removed with the awl engaged in the isthmus of the femoral canal. The shaft of the awl may now be used as an axial guide coinciding with the long axis of the femur. The Box Chisel is cannulated so that it slides over the shaft of the awl, removing a wedge of bone at the medial base of the greater trochanter (**Figure 5**).

Reaming with the Cylindrical Distal Reamers progresses sequentially after use of the Starter Awl.

Note: To reduce the potential for femoral fracture, it is recommended that areas of defects in the femur are prophylactically cabled prior to reaming and stem insertion. Dall-Miles™ Cables work well to assist the surgeon in this step.

Clear Out Reamer Use

The Clear Out Reamer is used to open up the proximal portion of the canal when preparing for 11mm, 12mm, and 13mm cylindrical distal stems (both straight and bowed, Fluted or Plasma). The Clear Out Reamer is used after the Starter Awl and before the Cylindrical Distal Reamers (**Figure 6**). The function of this reamer is two-fold. First, it prepares the canal for the tapered junction of the 11mm, 12mm, and 13mm stems since the tapered junction diameter is slightly larger than 13mm. Second, it prepares the canal to accept the 19mm Proximal Cone Reamer.

The reamer is inserted into the canal until the correct depth marking on the shaft aligns with the tip of the greater trochanter. When preparing for a Cone Body, the line corresponding to the preoperatively templated Cone Body (+0mm (STD), +10mm, +20mm, or +30mm) should align with the tip of the greater trochanter.

IMPORTANT: Adjunctive proximal fixation/support is *required* for stem diameters of 11mm, 12mm, and 13mm, and is *recommended* for stem diameters of 14mm and larger.

Figure 5

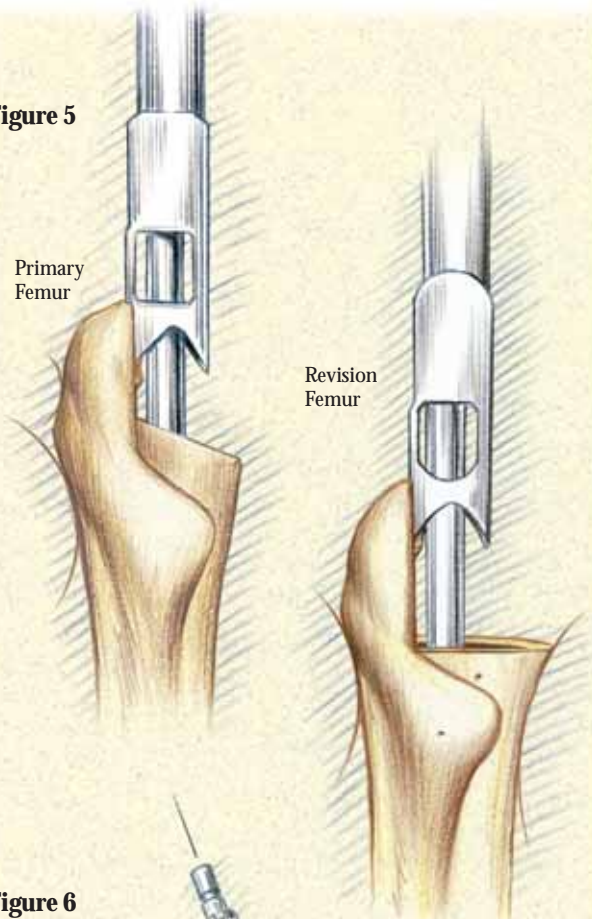
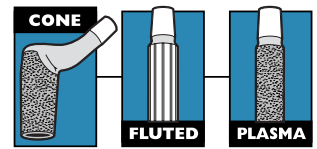


Figure 6





Distal Reaming – Fluted & Plasma Straight Stems

Use of the Cylindrical Distal Reamer -
127mm & 167mm Straight Stems

Cylindrical distal reaming for the 127mm or 167mm Fluted & Plasma Straight Distal Stems can be accomplished by use of a T-Handle (**Figure 7**) or on power (**Figure 8**). Select the diameter of a Cylindrical Distal Reamer starting with a size two millimeters smaller than the templated size. The reamer diameters are available in 0.5mm increments from 10.0mm - 26.0mm. There are two bold depth marking grooves on the reamers, 200mm and 240mm, and markings for the +10mm, +20mm, and +30mm resection levels. Measure the distance from the tip of the greater trochanter to the tip of the 127mm and 167mm distal stems.

Note that the tip of the greater trochanter is approximately at the same level as the center of rotation of the femoral head. Therefore, the depth markings also correspond to the distance from the center of a +0mm (STD) Femoral Head implant on the +0mm (STD) Cone Body to the tip of the 127mm or 167mm Fluted & Plasma Distal Stems.

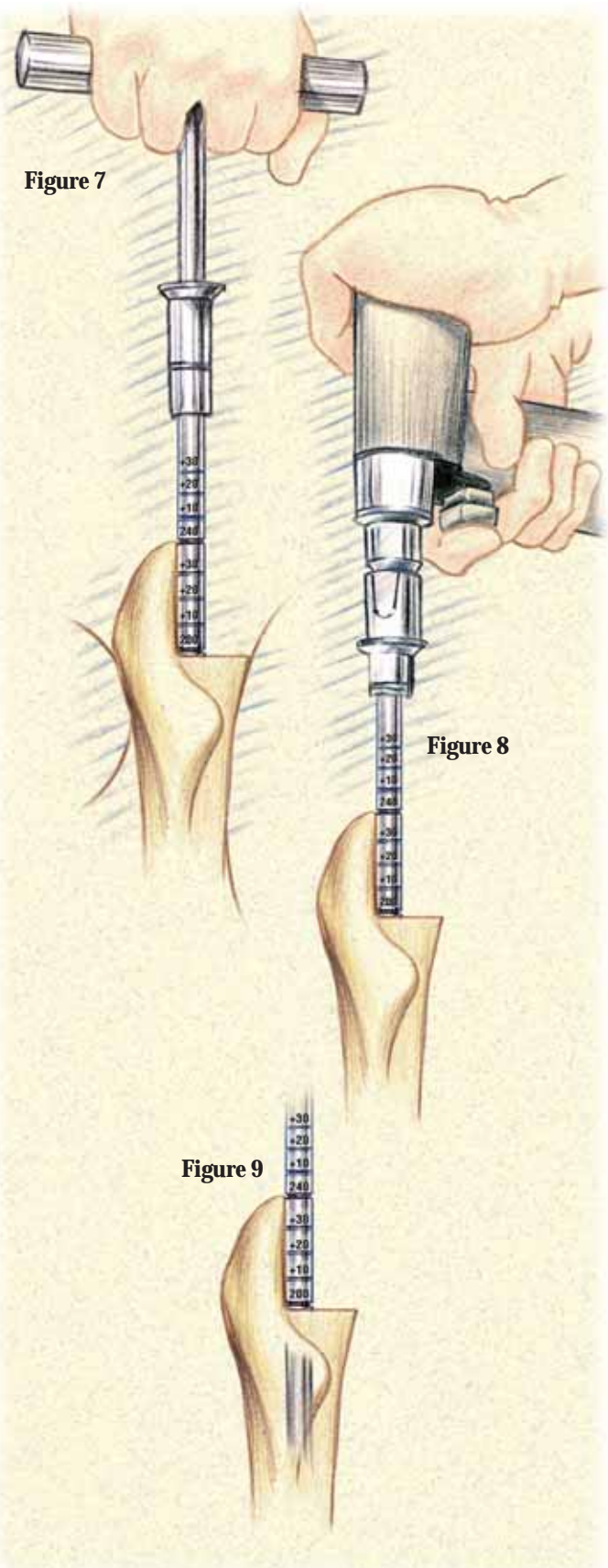
If the greater trochanter is off or not present, the measurements made during preoperative templating are necessary to determine the approximate location of the greater trochanter or head center. Alternately, measurements may be taken from an X-ray of the contralateral side.

Ream until the desired stem length depth groove (200mm or 240mm) aligns with the tip of the greater trochanter, or other landmark as planned during preoperative templating (**Figure 9**).

Note: Depending on bone quality and surgeon preference, the surgeon may choose to ream line-to-line, or under-ream for the Fluted & Plasma Distal Stems. If under-reaming, the final reamer size should be .5mm to 1mm smaller than the desired stem diameter.

Note: For the 127mm Straight Fluted or Plasma Distal Stems, reaming to at least 200mm is recommended.

Note: For the 167mm Straight Fluted or Plasma Distal Stems, reaming to at least 240mm is recommended.



Restoration® Modular Surgical Protocol

Distal Reaming – Fluted & Plasma Straight Stems (continued)

Use of the Cylindrical Distal Reamer - 127mm & 167mm Straight Stems (continued)
Progressively ream until resistance accompanied by cortical chatter is encountered. The reamers must be advanced into the femoral canal until the appropriate depth markings align with the tip of the greater trochanter, or approximate center of rotation.

If good cortical contact is not achieved, increase the reamer diameter in 0.5mm increments and insert only as deep as the 200mm or 240mm lines based on distal stem templating.

Suggestion: As in the Preoperative Planning Section, it is recommended that the femoral canal be reamed to the +0mm (STD) Cone Body level so that there are three remaining Cone Body height options (+10mm, +20mm, and +30mm) available during stem insertion.

Note: Intraoperative X-rays are valuable to gauge the position of the distal end of the Cylindrical Distal Reamers relative to the anterior bow of the femur.

Use of Flexible Reamers – 167mm, 217mm, 267mm & 317mm Bowed Long Stems

Flexible Reamers are used to prepare the distal canal to accept the anteriorly Bowed Fluted or Plasma long stem implants - 167mm, 217mm, 267mm, and 317mm (**Figures 10 and 11**). To determine the appropriate size Flexible Reamer, it is necessary to know the distal stem diameter planned for preoperatively. Select the diameter of a Flexible Reamer starting with a size two millimeters smaller than the templated size.

Note: It is important to use Flexible Reamers that are available in 0.5mm increments only. Flexible Reamers should always be used with a guide wire for guidance and removal in the event the reamer becomes lodged.

Reaming should progress sequentially up by 0.5mm increments under power to the closest reamer size corresponding with the stem size indicated for the patient. Ream until resistance accompanied by cortical chatter is encountered and the appropriate stem length depth is also achieved. In some instances, the curvature of the prepared canal may prevent the prosthesis from seating properly. At this point, the surgeon may choose to additionally ream 1mm to 2mm greater than the distal diameter of the intended stem. The full size Flexible Reamers correspond to the stem diameters of the Fluted & Plasma Distal Stems. Review charts on page 3 for all stem sizes.

Figure 10

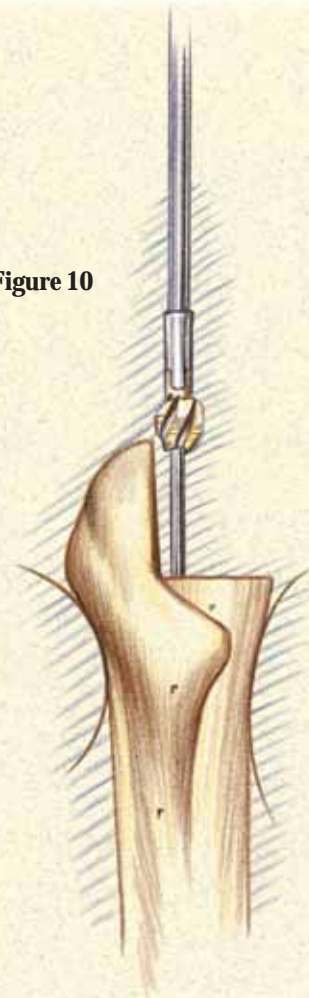
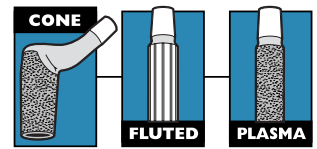


Figure 11





Preparing for the Cone Body

Insertion of Proximal Cone Reamers

The Cone Bodies are prepared by Proximal Cone Reamers and are available in 7 diameters: 19mm, 21mm, 23mm, 25mm, 27mm, 29mm, and 31mm. These diameters are measured at the most proximal level of the coating on the medial side of the Cone Body implant.

Two methods of reaming with the Proximal Cone Reamers are available.

Method 1 – Straight Stem

Attach the Proximal Cone Reamer to a power source and advance it over the final Cylindrical Distal Reamer. Starting with the 19mm Proximal Cone Reamer, commence proximal preparation for the Cone Body. Make note of the +0mm (STD), +10mm, +20mm, and +30mm reamer grooves, using the tip of the greater trochanter as the stopping point, since this will dictate the Cone Body height to be used (**Figure 12**). If another landmark is used, note that the Proximal Cone Reamer grooves generally correspond with the femoral head center.

Method 2 – Bowed Stem

Insert the Fluted or Plasma Bowed Distal Stem to its appropriate seating level, attach the Cone Reamer Guidepost, and tighten with the 5mm Hex Driver. Attach the Proximal Cone Reamer to a power source, and advance it over the Reamer Guidepost. Begin reaming with the 19mm Proximal Cone Reamer and advance the Cone Reamer over the Guidepost until it bottoms out on the post and it is impossible to advance the reamer further - visualize this by aligning the Alignment Groove on the Guidepost with the Alignment Groove on the reamer or view the top of the proximal slot, which when fully seated, will show no gap between the reamer and Guidepost (**Figure 13**).

Note: The predetermined head center marking on the Proximal Cone Reamer will generally align with the tip of the greater trochanter.

Proximal Cone Reaming progresses in 2mm increments until satisfactory contact within the trochanteric region is felt. Make note of the +10mm, +20mm, +30mm reamer grooves, since this will dictate the Cone Body height to be used. At this point, the surgeon has the option of performing a trial reduction or inserting the final implants.

WARNING: Failure to fully seat the Cone Reamer Guidepost, or failure to fully bottom out the Proximal Cone Reamer on the Guidepost, may prevent proper preparation of the bone for the Cone Body.

Figure 12



Figure 13



Restoration® Modular Surgical Protocol

Trial Reduction – Cone Body Trials with Fluted & Plasma Distal Stem Trials

Trial Reduction with Cone Body Trial and Distal Stem Trials – Optional

Once cylindrical distal and proximal cone reaming has been accomplished, a Cone Body Trial can be assembled to the 127mm or the 167mm Straight Distal Stem Trial or 167mm, 217mm, 267mm, or 317mm Bowed Distal Stem Trial, to assess fit of the proximal and distal components (**Figure 14**).

The Cone Body Trial offers a slightly undersized fit to the Cone Body implant. The 127mm and 167mm Straight Distal Stem Trials offer a slight (1mm) oversize (spline) portion to assist in stabilization during trial reduction - the remainder of the trial is line-to-line, i.e., 16mm reamer = 16mm trial.

The Bowed Distal Stem Trials (167mm, 217mm, 267mm, 317mm) are available in whole 1mm increments.

For Fluted stems, they match the actual stem diameter measured at the outside of the flutes. For Plasma stems, the Trials match the actual implant geometry minus the Plasma Spray with PureFix™ HA.

Note: The Bowed Distal Stem Trials do not have the oversized spline portion.

Assemble Cone Body Trial to Straight Distal Stem Trial

Position the appropriate Cone Body Trial with the integral locking bolt onto the Distal Stem Trial. Tighten the locking bolt with the 8mm Hex Driver, Version Control Stem Inserter, or Distal Stem Inserter (**Figure 15**). Excessive torque is not required when tightening. Insert into the femur and assess distal and proximal fit, leg length, range of motion, etc.

After this point, the final implants are ready for insertion.

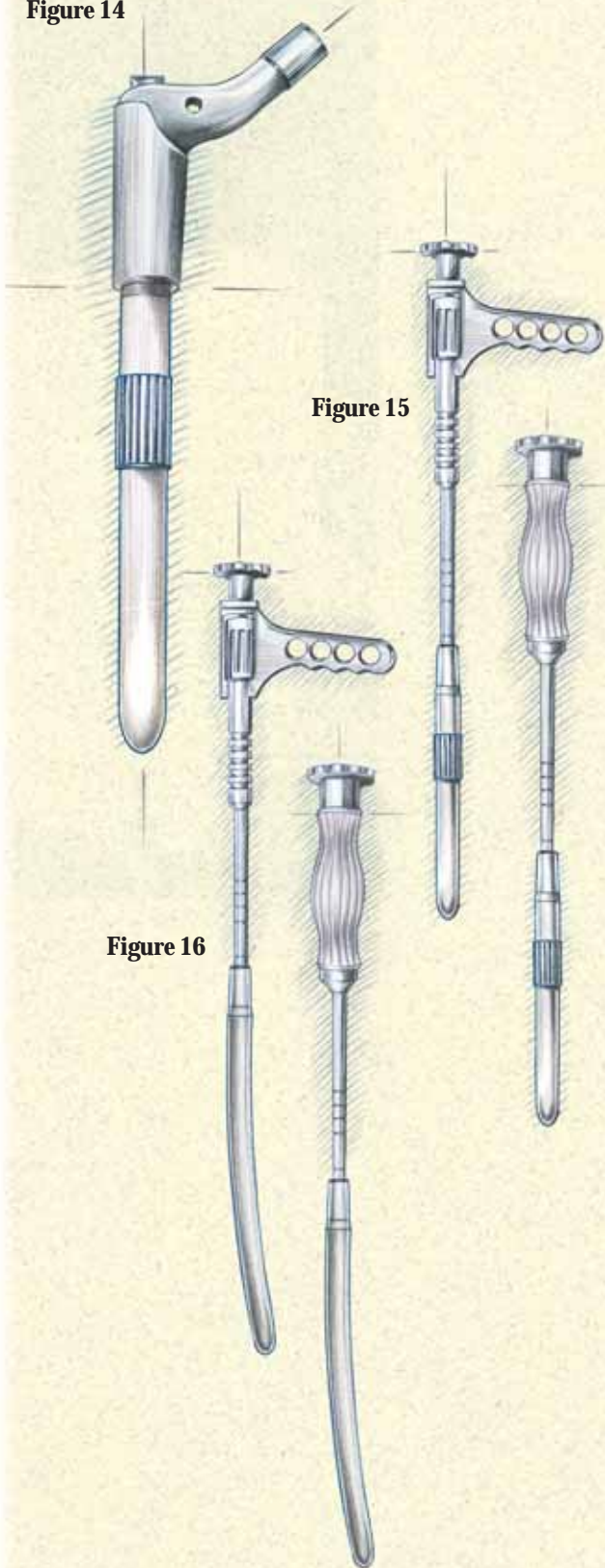
Trial Reduction with Bowed Trials

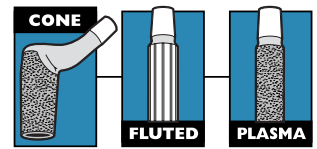
The Cone Body Trials/Bowed Distal Stem Trials are available to evaluate prosthetic stem size, biomechanical function, and implant stability prior to final insertion of the Bowed Stem implants. Optional Bowed Stem Trials are not necessarily identical in size and shape to the intended prosthesis and thus can only provide an estimation of the distal fit of the intended stem. The Bowed Stem Trials are inserted with the Version Control Stem Inserter or Distal Stem Inserter (**Figure 16**).

After this point, the final implants are ready for insertion.

Note: The bowed femoral canal, which is prepared by Flexible Reamers, may be slightly mismatched to the bow of the prosthesis.

Figure 14





Implant Insertion – Version Control Stem Inserter & Distal Stem Inserter w/Fluted & Plasma Distal Stems

Distal Stem Insertion

There are two options for inserting distal stems, the Version Control Stem Inserter (**Figure 17**) and the Distal Stem Inserter (**Figure 18**).

The Version Control Stem Inserter has a removable sleeve which can be used for distal stem impaction (alone) or impaction of the proximal body and distal stem together (**Figure 19**). This feature is especially useful when impacting a long, bowed distal stem with a Cone Body. The two components are held independent of each other (separated by 3mm - 5mm) upon impaction. This allows the distal stem to rotate freely upon impaction and give the surgeon the option of placing the Cone Body in the most appropriate anteversion required for the patient. See page 19 for more detail on this inserter.

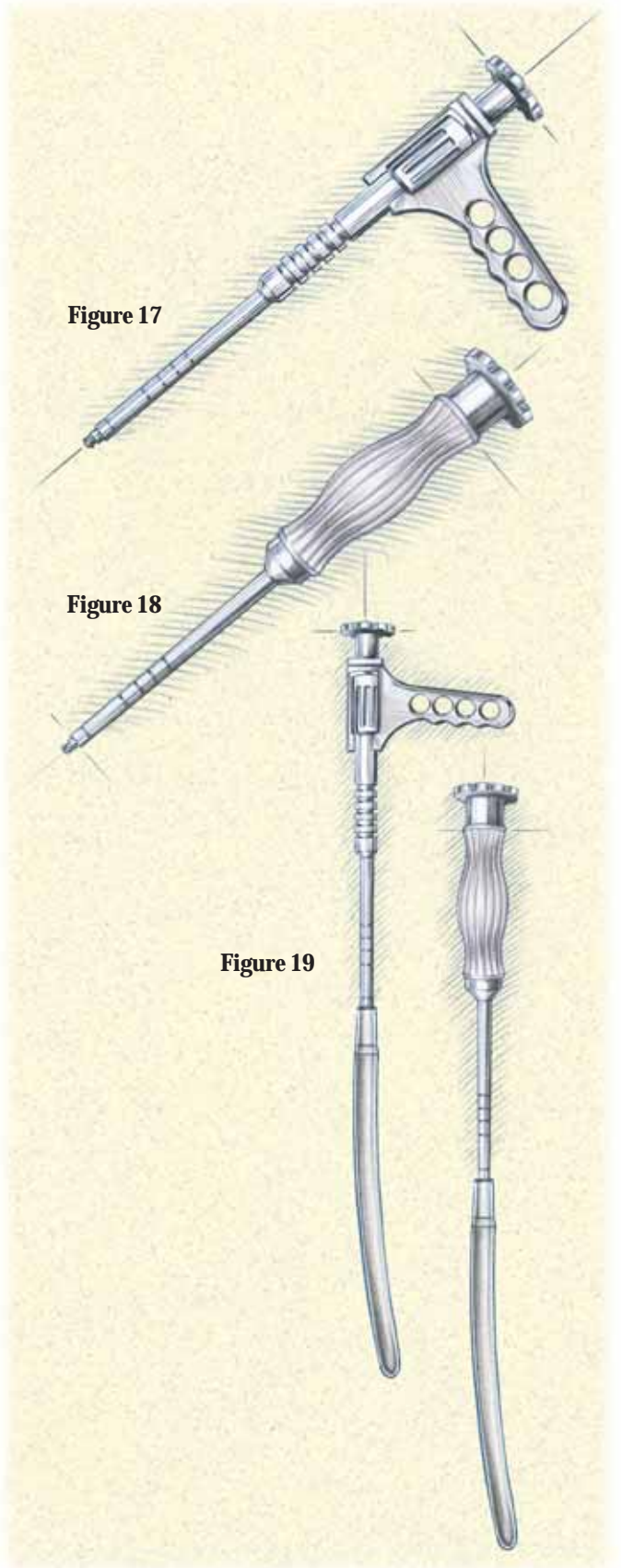
The Distal Stem Inserter is used only for distal stem impaction.

Thread the appropriate Fluted or Plasma Distal Stem onto either Distal Stem Inserter. The distal end of each inserter has a hex geometry with a spring-loaded threaded end that mates with a corresponding hex geometry on the stem. Make sure that the distal tip of the chosen Distal Stem Inserter is correctly aligned with the hex orientation feature of the insertion hole of the implant. Fully and securely attach the instrument to the distal stem by turning the locking knob clockwise.

Insert the Distal Stem

Both Stem Inserters have four depth marking grooves that correspond to the center of a +0mm (STD) Femoral Head implant on each of the four Cone Bodies (+0mm (STD), +10mm, +20mm, and +30mm). The distal-most Cone Body groove corresponds to the center of the +0mm (STD) Cone Body with a +0mm (STD) Femoral Head in place.

Note: Preoperative planning should have ensured that the tip of the distal stem will pass any distal defects by two to three canal diameters and will have 10cm - 12cm satisfactory mechanical stability. Make sure that sufficient distal fixation is attained with all Fluted or Plasma Distal Stems, especially those that are significantly larger than the templated stem size.



Restoration® Modular Surgical Protocol

Implant Insertion – Fluted & Plasma Distal Stems (continued)

Fluted Distal Stems

Impact the Fluted Distal Stem into the femoral canal until the stem achieves rotational stability and is positioned at the +0mm (STD) seating level on the impactor. The Fluted Distal Stem offers limited axial stability, so it is important to stop inserting the stem upon reaching the +0mm (STD) Cone Body seating level (**Figure 20**).

Plasma Distal Stems

Impact the Plasma Distal Stem into the femoral canal until the stem achieves rotational stability and axial stability and is positioned at the +0mm (STD) seating level on the impactor.

The four depth grooves will determine which Cone Body length will be used (+0mm (STD), +10mm, +20mm, or +30mm) when aligned with the tip of the greater trochanter.

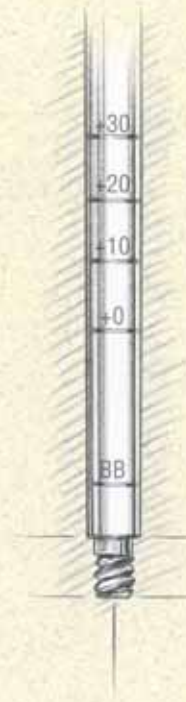
Generally, the depth groove of the Stem Inserter corresponds to the measurement taken during preoperative templating, however, it may be one of the other levels.

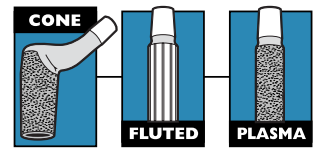
The Fluted or Plasma Distal Stem may advance further into the canal than originally templated and reamed. Thus, four Cone Bodies are available to restore the proper leg length.

If the distal stem advances beyond the +30mm Cone Body level, ream up with the distal reamers until rotational (and axial) stability is achieved. Perform a trial reduction and insert the corresponding distal diameter stem.

Note: The Cone Body and straight Fluted or Plasma Distal Stem combination may be assembled and impacted together on the back table prior to insertion into the femur.

Figure 20





Cone Body Trial – Fluted & Plasma Distal Stems

Assemble the Appropriate Cone Body Trial to Cylindrical Distal Stem
 Select the Cone Body Trial corresponding both to the final Proximal Cone Reamer diameter and to the proper height based on the reamer grooves. Assemble the 8mm Hex Locking Bolt Driver Shaft to the T-Handle (**Figure 21**). Position the appropriate Cone Body Trial with the integral locking bolt onto the Distal Stem. Determine the appropriate version for the trial and then tighten the locking bolt with the 8mm Hex Locking Bolt Driver assembly or the Distal Stem Inserter. Excessive torque is not required when tightening (**Figure 22**).

Attach Head Trial
 Select the head diameter (22mm, 26mm, 28mm, 32mm, or 36mm) according to surgeon preference. The Femoral Head Trials have a circumferential groove, which identifies the level of the center of rotation. Select the appropriate Femoral Head Trial based on preoperative templating from the chart below or surgical need. Attach the Femoral Head Trial to the Cone Body Trial (**Figure 23**). The head center of the +0mm (STD) Head Trial, when attached to the trial construct, should correspond with the tip of the greater trochanter.

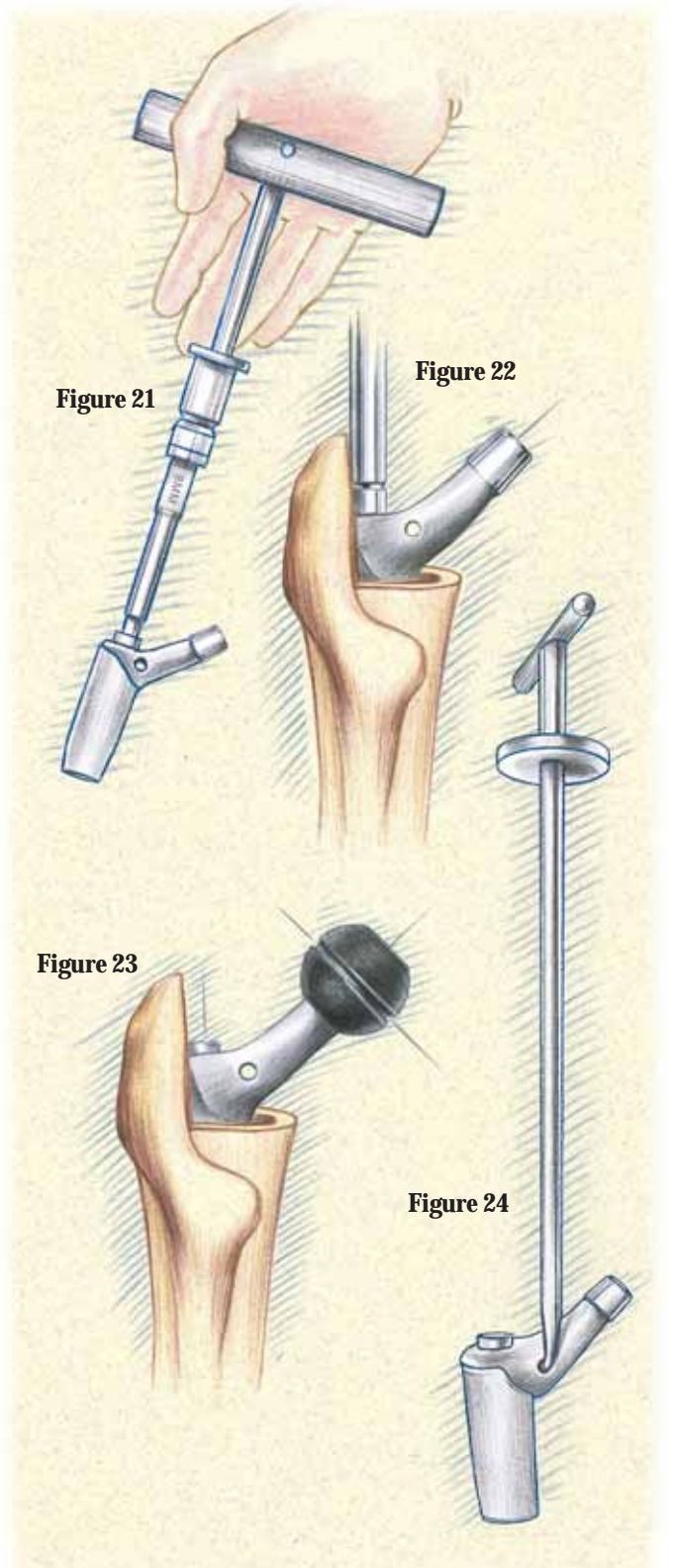
CoCr Head Compatibility	
22mm	+0mm (STD), +3mm, +8mm
26mm	-3mm, +0mm (STD), +4mm, +8mm, +12mm
28mm	-4mm, +0mm (STD), +4mm, +8mm, +12mm
32mm	-4mm, +0mm (STD), +4mm, +8mm, +12mm
36mm	-5mm, +0mm (STD), +5mm, +10mm
Alumina Ceramic Head Compatibility	
28mm	-2.7mm, +0mm (STD), +4mm
32mm	-4mm, +0mm (STD), +4mm
36mm	-5mm, +0mm (STD), +5mm

IMPORTANT: Do not use the +16mm Femoral Head with any Restoration® Modular Hip combination.

Trial Reduction
 Perform a trial reduction and assess the hip for stability, leg length, and overall range of motion. Adjust the Cone Body Trial as necessary to achieve maximum joint stability. Mark the desired anteversion on the femur with methylene blue, in line with the neck. Carefully remove the Femoral Head Trial and Cone Body Trial.

If additional leg length is required, a longer proximal body may be used so long as the current trial is not a +30mm length body.

Additionally, if the trial reduction indicates that a Femoral Head with a “skirt” is required, it may be possible to increase the body height by 10mm and use a shorter Femoral Head to produce an equivalent neck length without using a “skirted” Femoral Head. This may be beneficial in increasing range of motion.



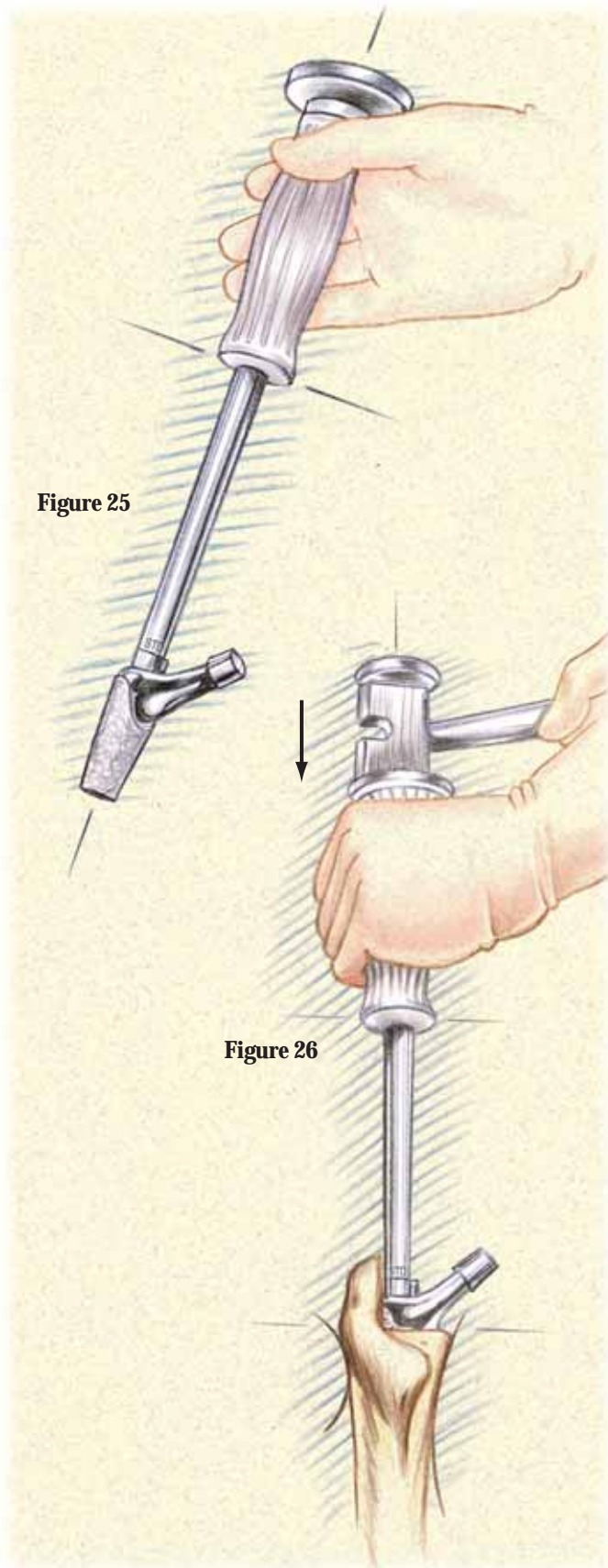
Note: If the Cone Body Trial becomes fixed in the canal, it may be removed with a bone hook or Trial Body Removal Device (Figure 24).

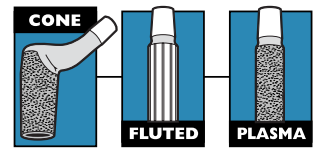
Restoration® Modular Surgical Protocol

Cone Body Impaction

Cone Body Impaction

Based on the trial reduction, select the appropriate size Cone Body implant. Lavage the area surrounding the proximal taper of the distal stem. Wipe the cylindrical distal stem trunnion clean, and align the neck and trunnion of the Cone Body implant with the methylene blue marking, indicating the desired anteversion on the distal stem trunnion. Attach the Proximal Body Impactor to the Cone Body (**Figure 25**) and impact the Cone Body implant onto the trunnion of the distal stem maintaining proper anteversion. The impaction of the Cone Body onto the trunnion of the distal stem cold-welds the tapers, locking the components together (**Figure 26**).





Implant Insertion

Assemble Implants onto the Version Control Stem Inserter – Optional
 Attach the Cone Body onto the Proximal Impactor and lock it into the correct position on the Version Control Stem Inserter. The second position on the Version Control Stem Inserter corresponds to Cone Body sizes. When the Proximal Impactor is locked into the correct position it maintains a short gap (approximately 3mm - 5mm) between the Cone Body and distal stem tapers. Next, load the distal stem onto the tip of the Version Control Stem Inserter. Fully and securely attach the instrument to the distal stem with the thumb-wheel locking knob or hand knob.

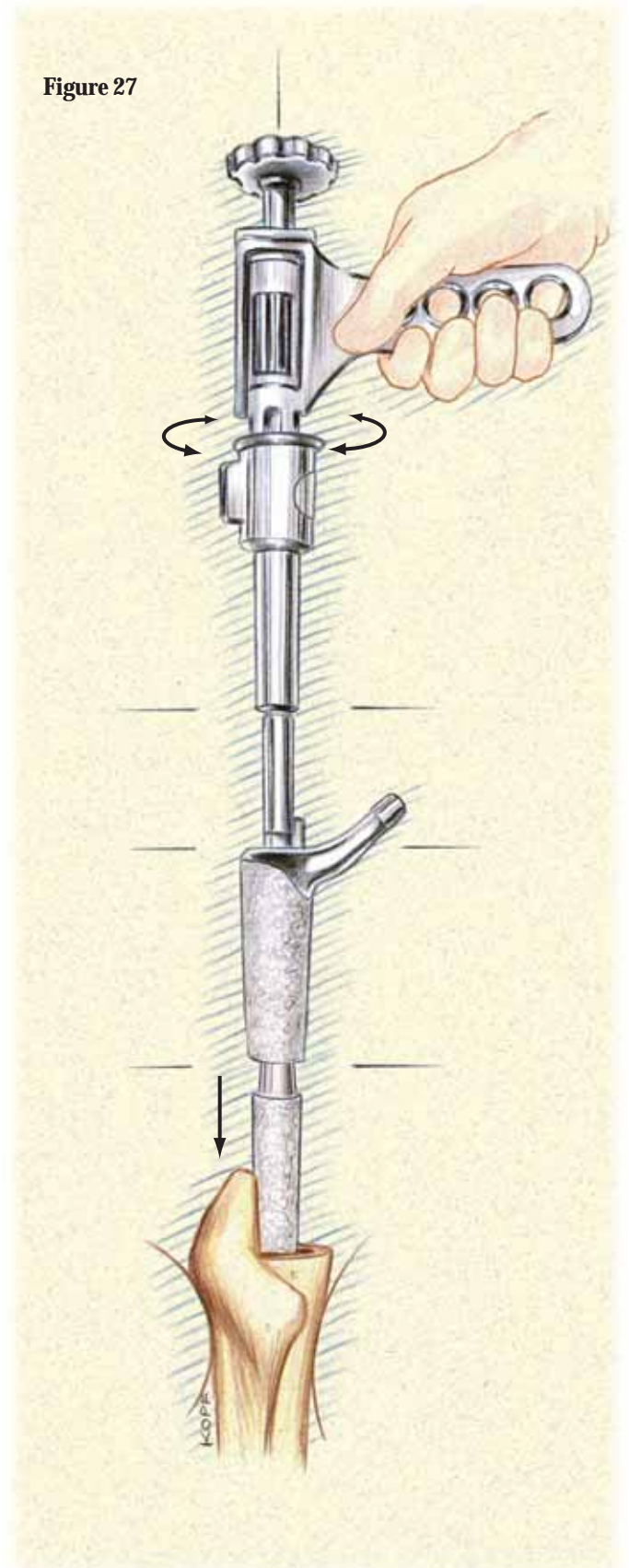
Insert the Cone Body and Distal Stem - Optional
 The Version Control Stem Inserter allows independent control of both the proximal Cone Body and distal stem during insertion (**Figure 27**).

As the construct is impacted, the handle of the Version Control Inserter controls the version of the distal stem while the grip of the Proximal Body Impactor independently controls the version of the proximal body. Impact the components into the femoral canal until the Cone Body lies approximately 1cm - 2cm proud of its final seating position. Detach the Version Control Stem Inserter from the distal stem and remove the instrument while simultaneously depressing the button on the Proximal Body Impactor. Impact the Proximal Body Impactor with a mallet to lock the proximal body and distal stem taper and drive the assembly to the final seating position.

If the Version Control Stem Inserter is utilized without the Proximal Body Impactor to seat the distal stem, the corresponding Cone Body height marking should align with the tip of the greater trochanter.

IMPORTANT: Do not fully seat the final implant before setting rotation; make a final assessment and then secure the body to the stem.

Figure 27



Restoration® Modular Surgical Protocol

Taper Lock Gauge/Bone Grafting

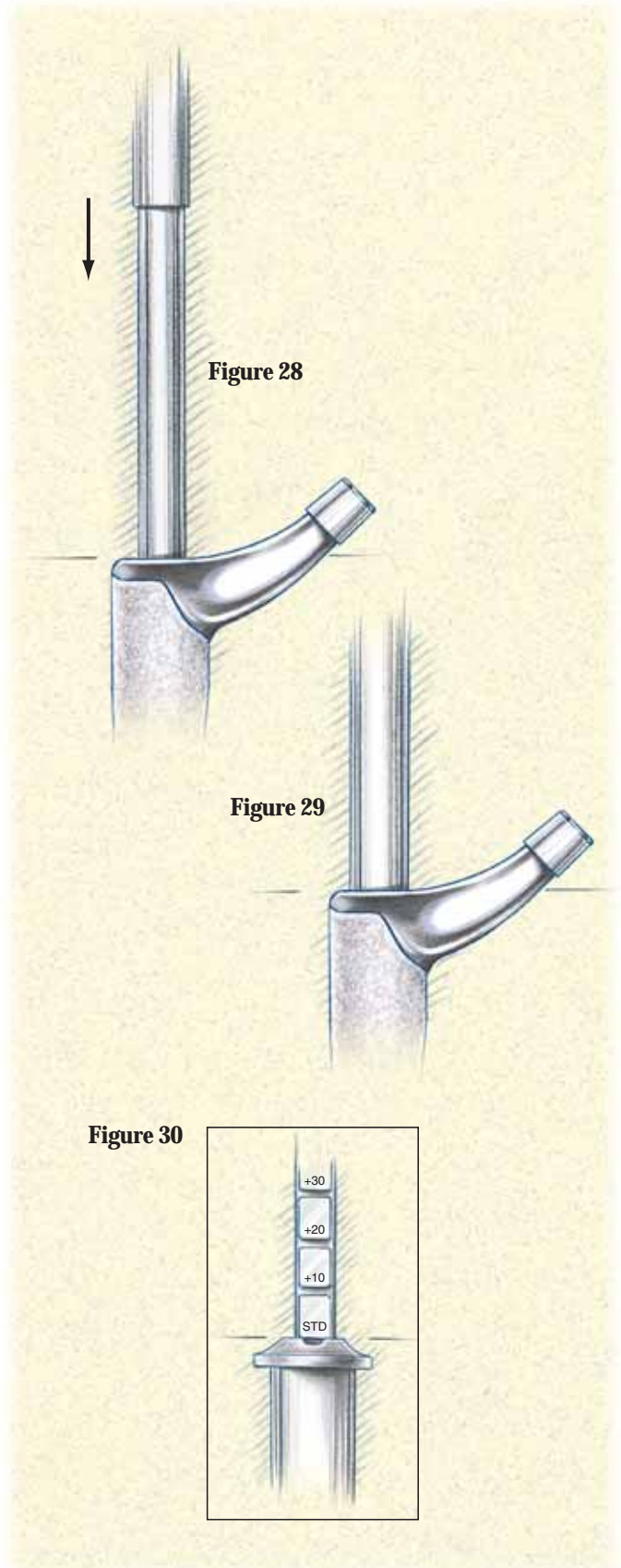
Taper Lock Gauge

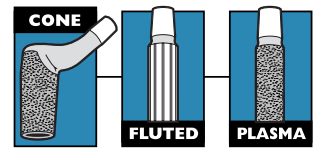
After the Cone Body has been impacted onto the distal stem, the Taper Lock Gauge can be used to assess proper engagement of the body with the stem. Insert the Taper Lock Gauge through the proximal body until it is seated on the distal stem (**Figure 28**). Slide the handle down until it is fully seated in the proximal body (**Figure 29**). The slotted indicator on the top of the handle will align within the groove corresponding to the Cone Body height implanted (+0mm (STD), +10mm, +20mm, +30mm) (**Figure 30**).

Note: If the indicator is outside the corresponding groove, it may be necessary to further impact the body, or re-ream the proximal femur to clear out any bone stock that may interfere with the body properly seating on the stem.

Bone Grafting

Femoral deficiencies should be planned for and appropriately addressed as discussed in the preoperative planning part of this protocol. If the femoral cortex above the diaphyseal stem fixation point is deficient, the surgeon should be prepared to apply cortical strut grafts to repair and strengthen the femur.





Locking Bolt Assembly and Tightening

Locking Bolt Assembly and Tightening

Place the Locking Bolt into the Cone Body and tighten the Locking Bolt with the 5mm Hex Locking Bolt Driver assembly (**Figure 31**). Assemble the Torque Wrench and Torque Wrench Adapter, and apply a minimum load of 150in-lb and a maximum load of 180in-lb torque to ensure that the Locking Bolt is sufficiently tightened (**Figure 32**). The Steady Handle must be used to hold the anteversion of the Cone Body in place while applying torque. The Steady Handle counter balances the torque applied to the bolt to ensure that only the implant and not the femur is torqued.

IMPORTANT: For Cone Body sizes 21mm - 31mm, when the body and stem tapers are fully engaged, the entire head of the locking bolt will be seen 1mm - 2mm above the shoulder of the Cone Body (Figure 33). For the 19mm Cone Body, when the body and stem tapers are fully engaged, the underside of the locking bolt head will be about 1mm below the shoulder of the Cone Body (Figure 34).

Note: The Fluted & Plasma Distal Stems have Spirallock® threads that will not loosen if the Locking Bolt is sufficiently tightened. The Spirallock® thread form reduces vibration loosening, provides a more uniform load distribution, reduces stress concentration, reduces fatigue failure, and eliminates the need for additional locking devices such as end caps.

Figure 31

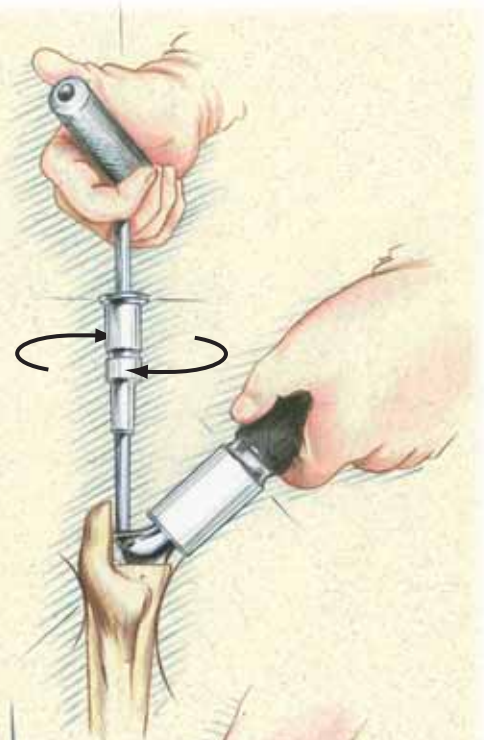


Figure 32

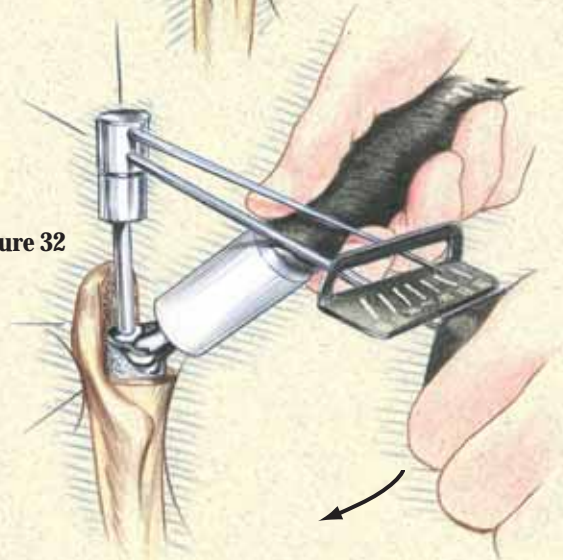
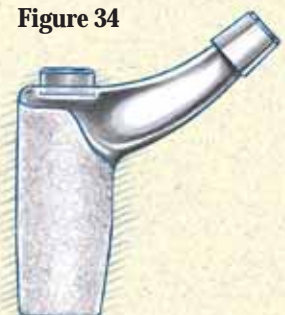


Figure 33



Figure 34



Restoration® Modular Surgical Protocol

Final Trial Reduction

Attach Head Trial

Select the head diameter (22mm, 26mm, 28mm, 32mm, or 36mm) according to surgeon preference. The Femoral Head Trials have a circumferential groove, which identifies the level of the center of rotation (**Figure 35**). Select the desired Femoral Head Trial based on trial reduction from the chart below. Attach the Femoral Head Trial to the Cone Body. The head center of the Femoral Head Trial, when attached to the implant construct, should correspond with the tip of the greater trochanter.

At this point, a final trial reduction can be performed using the attached Femoral Head Trial.

CoCr Head Compatibility	
22mm	+0mm (STD), +3mm, +8mm
26mm	-3mm, +0mm (STD), +4mm, +8mm, +12mm
28mm	-4mm, +0mm (STD), +4mm, +8mm, +12mm
32mm	-4mm, +0mm (STD), +4mm, +8mm, +12mm
36mm	-5mm, +0mm (STD), +5mm, +10mm
Alumina Ceramic Head Compatibility	
28mm	-2.7mm, +0mm (STD), +4mm
32mm	-4mm, +0mm (STD), +4mm
36mm	-5mm, +0mm (STD), +5mm

IMPORTANT: Do not use the +16mm Femoral Head with any Restoration® Modular Hip combination.

Impact Head onto Cone Body Trunnion

Select the appropriate size Stryker® Orthopaedics V40™ Femoral Head, wipe the V40™ trunnion clean, and impact the Femoral Head onto the trunnion with the Femoral Head Impactor. Two or three mallet blows to the impactor is sufficient to impact the Femoral Head onto the trunnion (**Figures 36 and 37**).

Reduce Joint and Close

Relocate the Femoral Head into the acetabular cup and check the stability and range of motion. The surgical site is then closed according to the standard procedure for the surgical approach chosen.

Postoperative Care

Postoperative care should progress according to surgeon preference and recommendation.

Figure 35

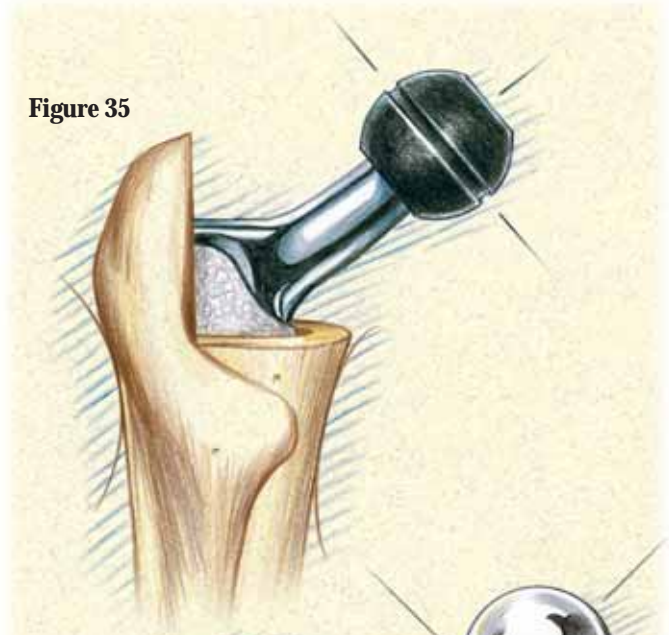


Figure 36

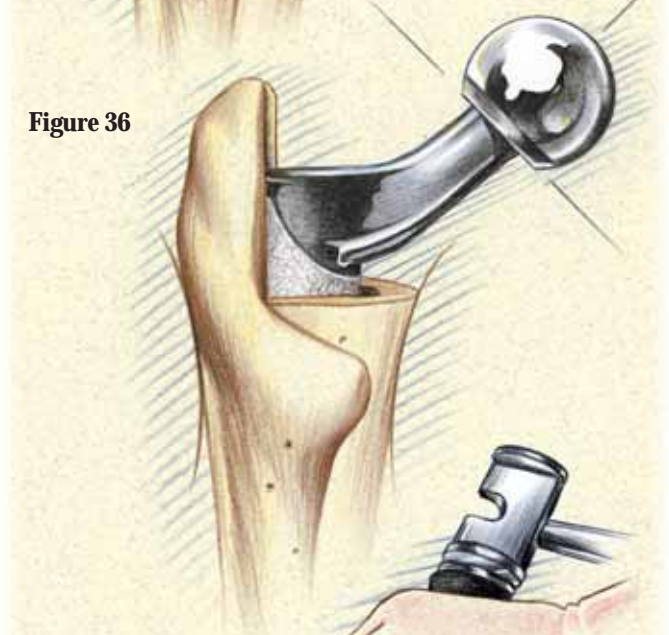
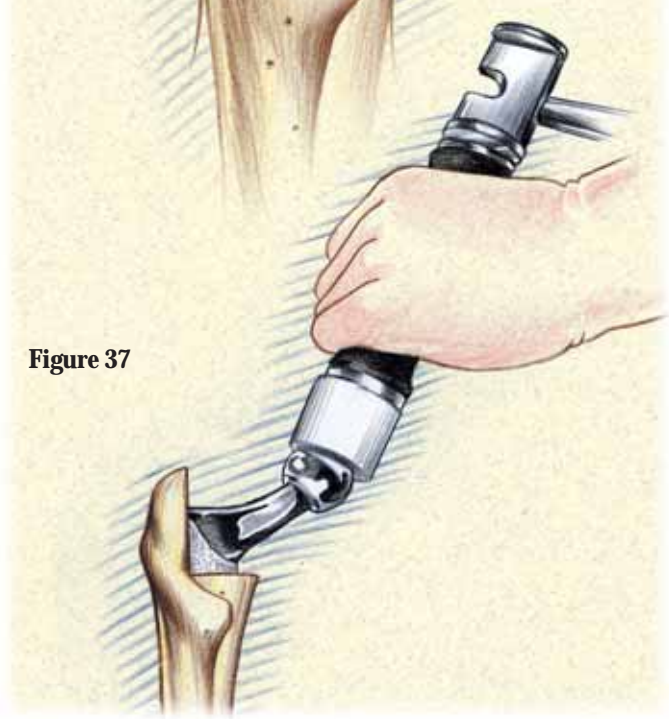
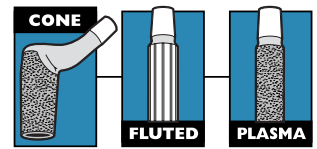


Figure 37





Restoration® Modular Cone Body/Fluted & Plasma Distal Stem Removal

If new components are to be disassembled during surgery (i.e., to readjust version) inspect the proximal body and distal stem closely for damage prior to re-impacting the body onto the distal stem. If the proximal body or distal stem shows damage, do not reuse the components but instead re-implant new, undamaged components.

Note: The Locking Bolt must be removed prior to using stem removal instruments (Figure 38).

Cone Body Removal

The Body/Stem Separator is made up of three parts: Jackscrew, Shaft Puller, and a reverse-thread Distal Collet (**Figure 39**). Two modular handles are also available for use with the Body/Stem Separator, which assist in counter-rotation when tightening with the T-Handle.

Unthread the Jackscrew completely from the Shaft Puller prior to inserting through the Cone Body. Ensure that the Distal Collet is fully threaded into the Shaft Puller, keeping in mind that the Collet and Shaft Puller are reverse-threaded. Insert the Shaft Puller/Distal Collet assembly through the Cone Body until the collet is fully inserted. An audible click will be heard along with a decrease in resistance upon full insertion.

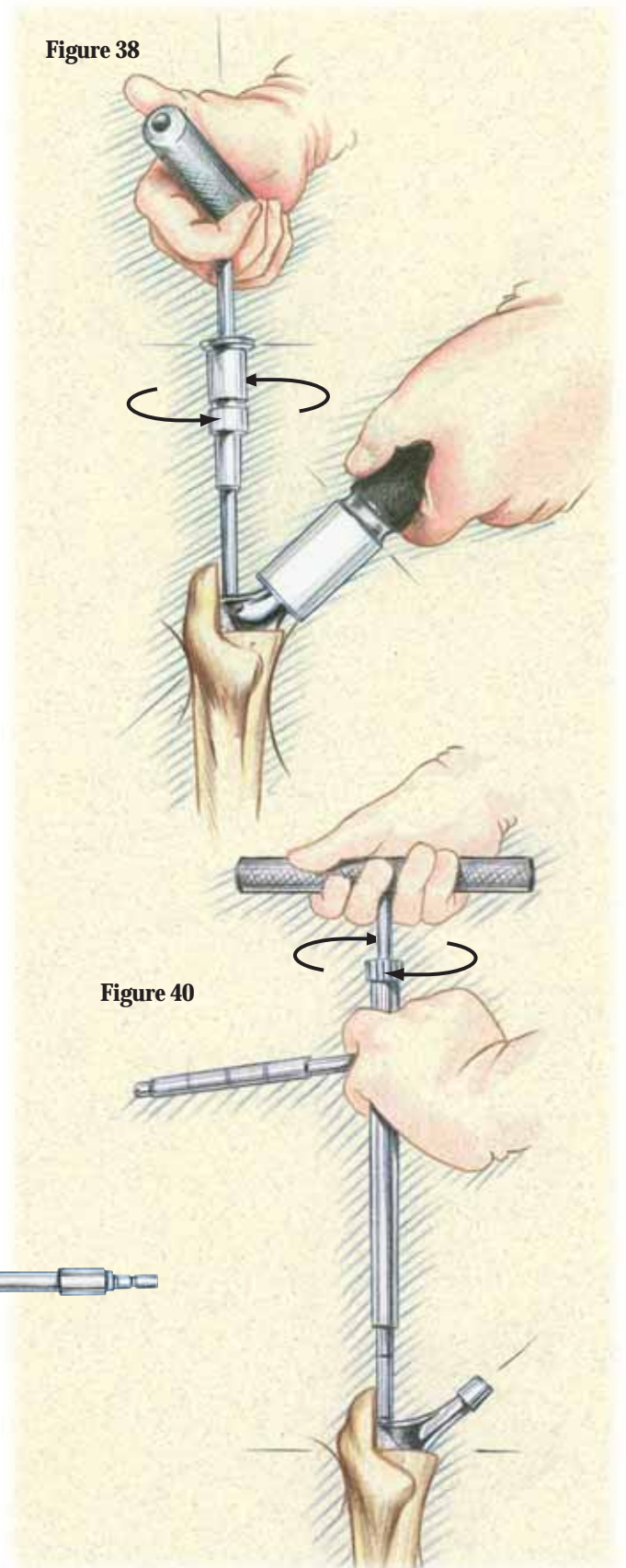
Thread the Jackscrew through the Shaft Puller/Distal Collet by hand until the Jackscrew cannot be advanced further. Insert the modular handle(s) into the upper hub of the Shaft Puller. The handles are spring-loaded and will engage when rotated to the correct position. Assemble the T-Handle to the Jackscrew and turn the T-Handle until the Cone Body disengages from the distal stem (**Figure 40**).

Note: In order to remove the body from the Shaft Puller assembly, remember that the Distal Collet is a REVERSE-THREAD, and must be completely removed from the assembly to release the body.

Figure 39



Figure 38



Restoration® Modular Surgical Protocol

Restoration® Modular Cone Body/Fluted & Plasma Distal Stem Removal (continued)

Distal Stem Removal

Assemble the Distal Stem Removal Adapter to the McReynolds Driver-Extractor. Thread the distal stem removal assembly into the insertion feature of the distal stem (**Figure 41**). Use the slap hammer to remove the distal stem from the canal.

Restoration® Modular

Cone Body/Fluted & Plasma Stem Removal

The Distal Stem Removal Adapter/McReynolds Driver-Extractor assembly may be threaded through the Cone Body into the distal stem to remove the entire stem assembly. Use the slap hammer to remove the stem assembly from the canal (**Figures 42 and 43**).

Figure 41

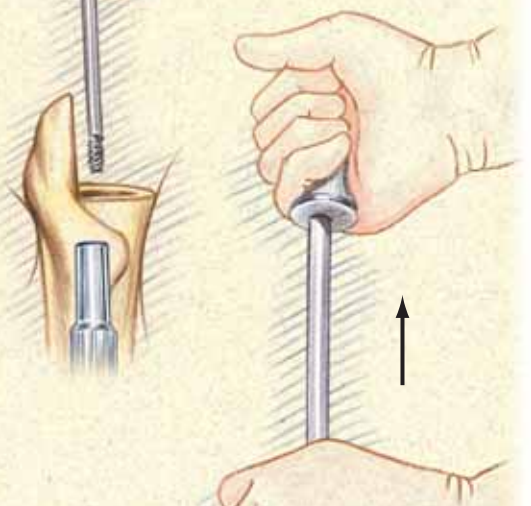
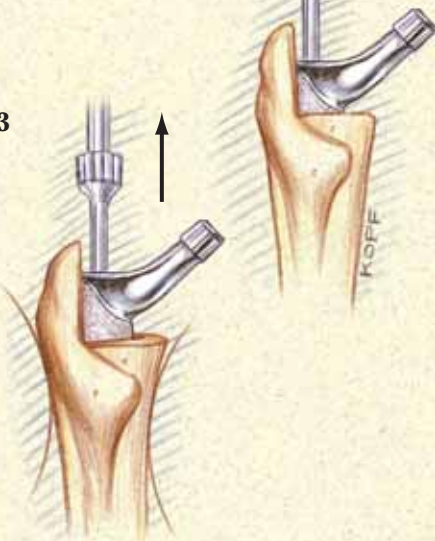


Figure 42

Figure 43



Joint Replacements

Trauma

Spine

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Orthobiologics

Instruments

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