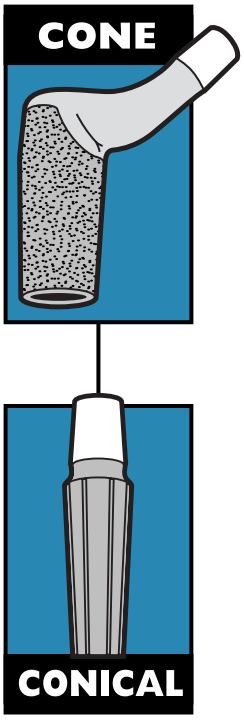
stryker

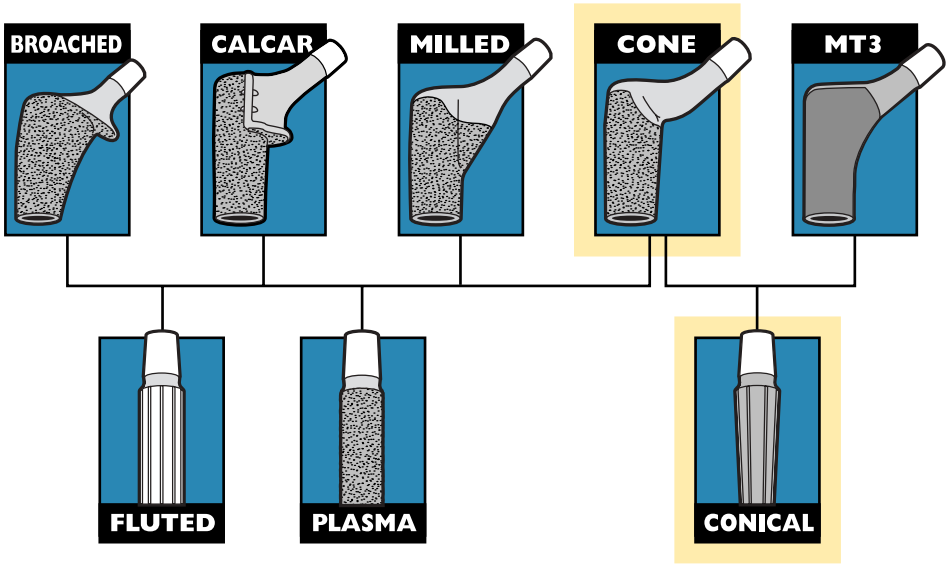
Orthopaedics

Restoration® Modular Revision Hip System

Surgical Protocol



Restoration® Modular Cone Body/Conical 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/Conical 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 bone proximal 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/Conical 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/Conical 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 primaries 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.)

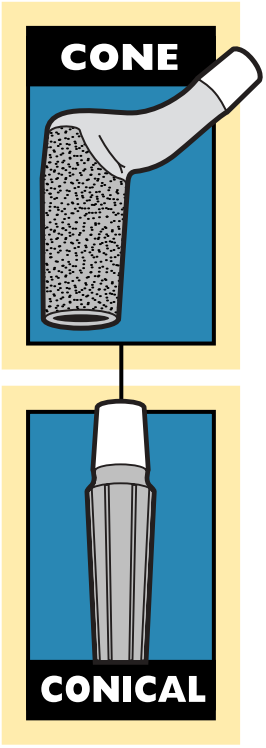
Cone Bodies accept CoCr V40™ Femoral Heads with diameters in 22mm, 26mm, 28mm, 32mm, and 36mm or Alumina Ceramic V40™ Femoral Heads with diameters in 28mm, 32mm, and 36mm.

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

The Conical Distal Stem is designed to provide immediate diaphyseal rotational and axial stability. These stems are available in three lengths – 155mm, 195mm, and 235mm. Each distal stem length comes in 15 fluted, conical diameters from 14mm to 28mm in 1mm increments. The 155mm and 195mm Conical Distal Stems are offered with a straight design option. The 195mm Conical Distal Stem is also offered with a bowed option. The 235mm Conical Distal Stem is only offered with a bowed option.

The total length of the Cone Body/Conical 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 three lengths of Conical Distal Stems. Review Sizing Charts for stem lengths on page 3.

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

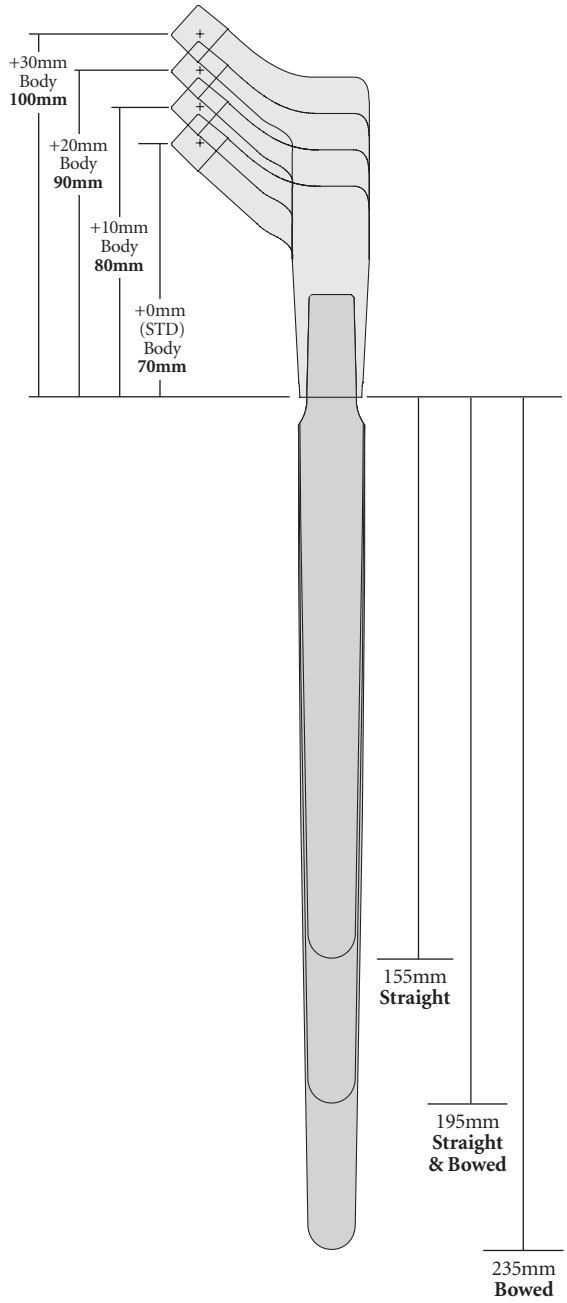
Cone Body Sizes	-4mm*	+0mm (STD)	+4mm	+8mm	+12mm
19mm	31mm	34mm	37mm	40mm	43mm
21mm	33mm	36mm	39mm	42mm	45mm
23mm	37mm	40mm	43mm	46mm	49mm
25mm	41mm	44mm	47mm	50mm	53mm
27mm	41mm	44mm	47mm	50mm	53mm
29mm	41mm	44mm	47mm	50mm	53mm
31mm	41mm	44mm	47mm	50mm	53mm

*Not available in 22mm or 26mm diameter head (see Head Compatibility chart on pages 16 or 19).

Cone Body/Conical Distal Stem Sizes†

Cone Body Sizes	Neck Angle	Distal Stem Lengths (mm)	Distal Stem Diameters
19mm 21mm 23mm 25mm 27mm 29mm 31mm	132°	155, 195, 235	14mm – 28mm in 1mm Increments

†Measured to outside of flutes, 120mm up from distal tip.



Cone Body/Conical Distal Stem Combined Overall Lengths**

Conical Distal Stem Sizes	Cone Body Heights			
	70mm +0mm (STD)	80mm +10mm	90mm +20mm	100mm +30mm
155mm Length 14mm-28mm dia. (Straight)	225mm	235mm	245mm	255mm
195mm Length 14mm-28mm dia. (Straight & Bowed)	265mm	275mm	285mm	295mm
235mm Length 14mm-28mm dia. (Bowed)	305mm	315mm	325mm	335mm

**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

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.

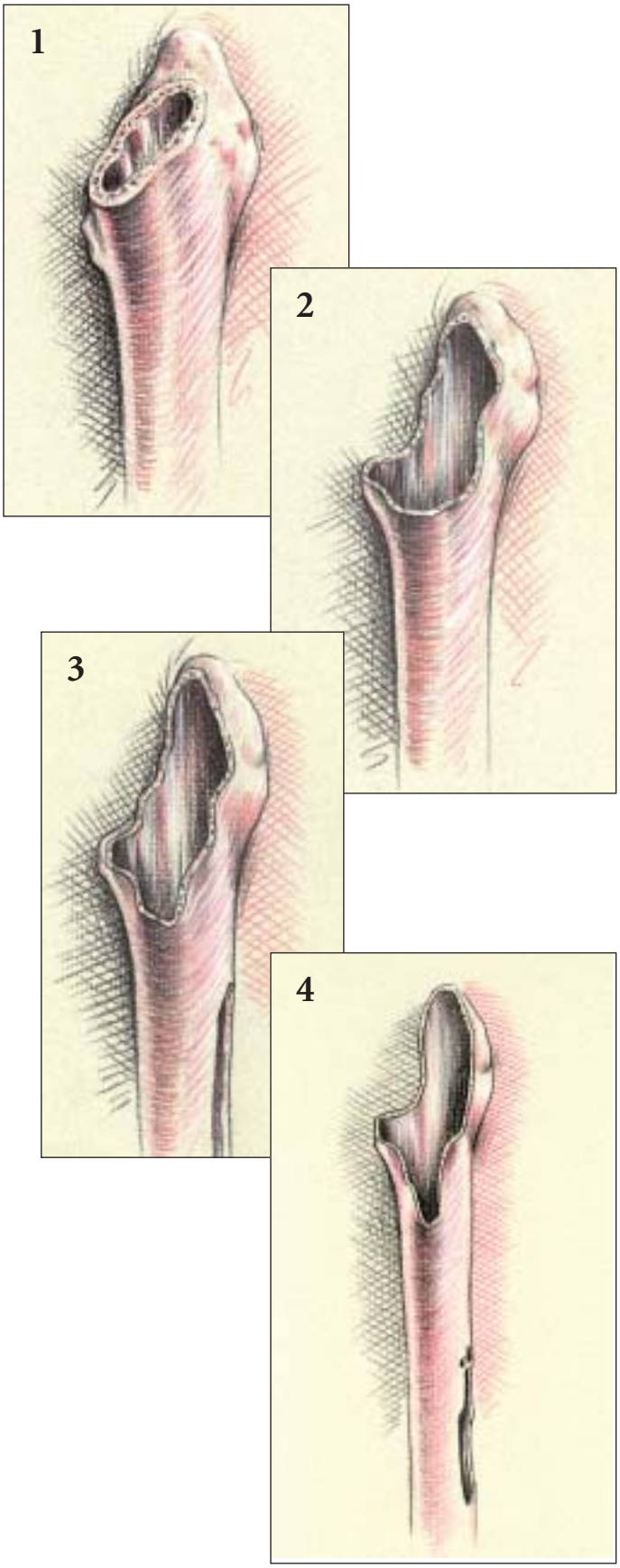
Type 2A - The calcar is non-supportive, but the diaphysis is still intact.

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

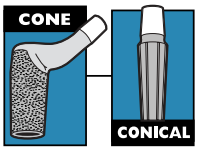
Type 2C - The calcar is non-supportive and the posteromedial part of the metaphysis is deficient, but the diaphysis is still intact.

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 cavitary 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 cavitary 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/Conical 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 Conical 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%.

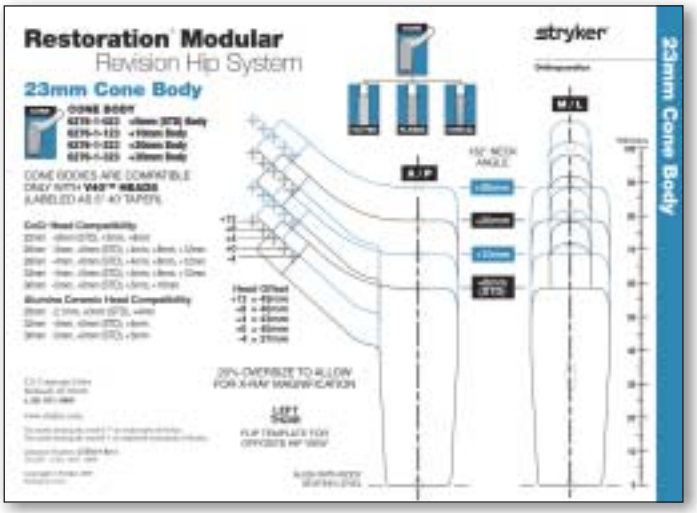
Preoperative planning is strongly recommended for leg length planning, measuring the length of the existing prosthesis being revised, predicting the potential use and type of trochanteric osteotomy, the Cone Body size and vertical offset, and the Conical Distal Stem diameter and length of the prosthesis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

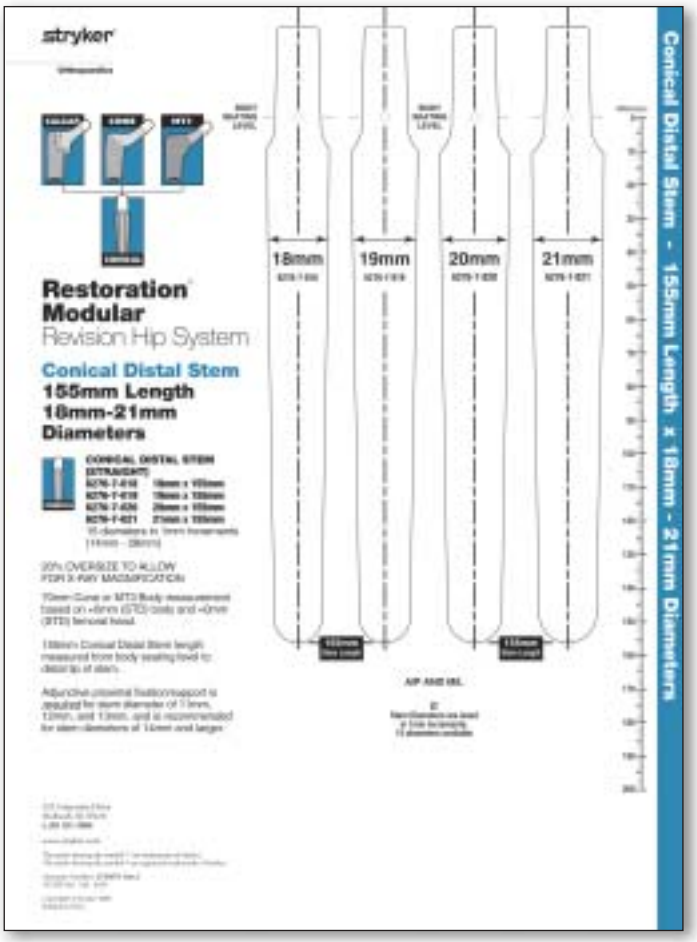
Anterior-Posterior (A/P) and Medial-Lateral (M/L) radiographs are necessary for X-ray templating. In cases of severe femoral compromise, a full A/P pelvic X-ray of the operative side as well as the contralateral side is helpful to assess the biomechanical requirements of the reconstruction. The lateral X-ray is informative in that it will show the anterior bow of the femur, which is useful when templating with the 155mm straight, 195mm straight and bowed, or 235mm 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.





Patient Selection

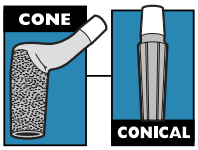
Proper implant selection is critical to the stability and longevity of the femoral stem implant in hip arthroplasty. Proper implant selection must consider design, fixation, and environmental variables including: patient weight, age, bone quality and size, activity level and preoperative level of health, 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 height 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 Conical Distal Stem diameter of the implant by establishing the region of the femoral cortices that appears to be free from defects that 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 Conical 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.

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, scar 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 Conical 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

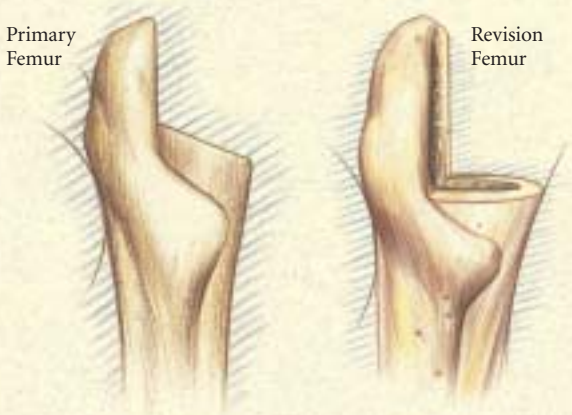
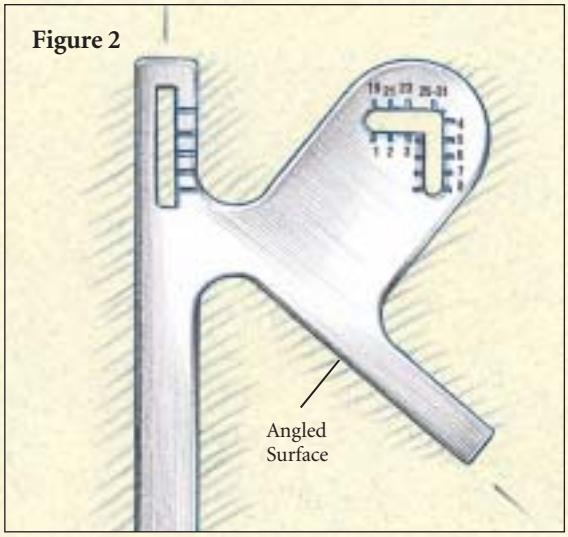
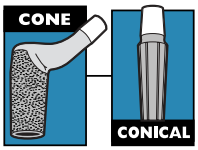


Figure 2





Box Chisel and Starter Awl

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**).

As a reference, the depth marking grooves on the Starter Awl are at the 200mm level and the 240mm level from the tip of the greater trochanter. Measurement for depth insertion of the Starter Awl when used with all Cone Body/Conical Distal Stems is at the tip of the greater trochanter.

Figure 3

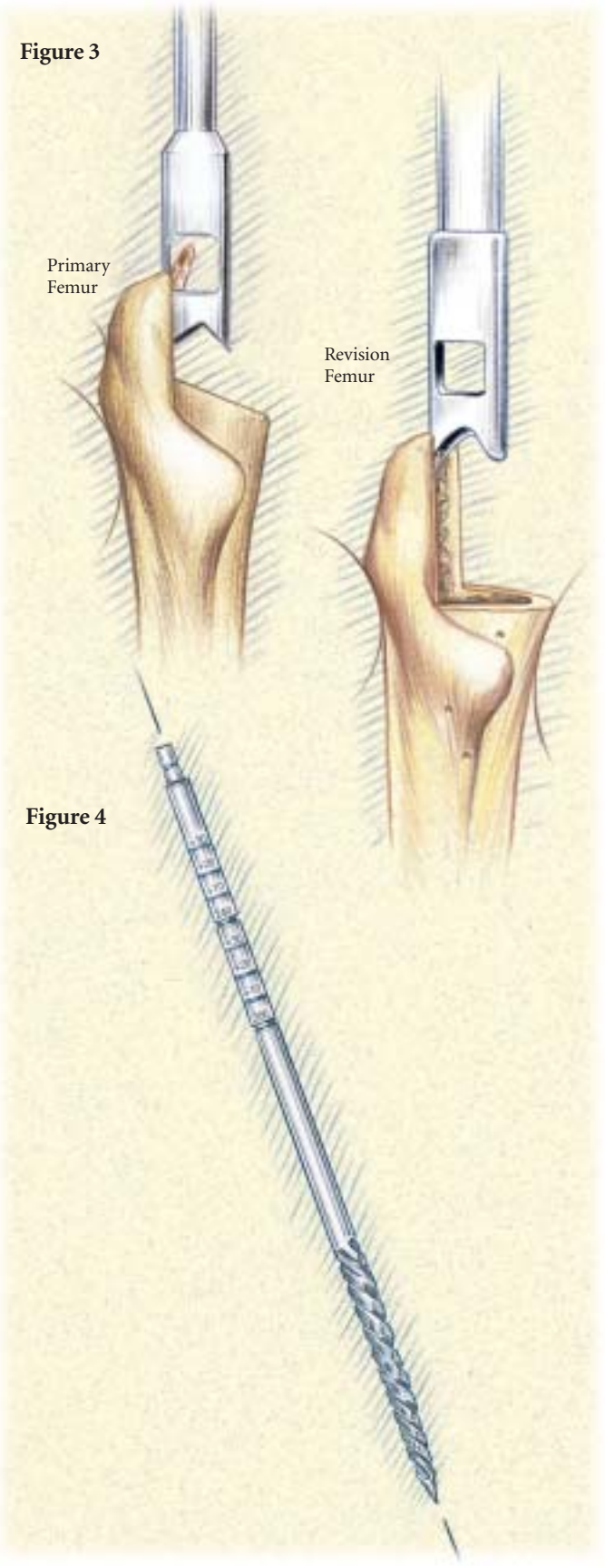


Figure 4

Box Chisel and Starter Awl (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 Conical 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 the 14mm Conical Distal Stems (both straight and bowed). The Clear Out Reamer is used after the Starter Awl and before the Conical Distal Reamers (**Figure 6**). The function of this reamer is to prepare the canal to accept the initial 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 the 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

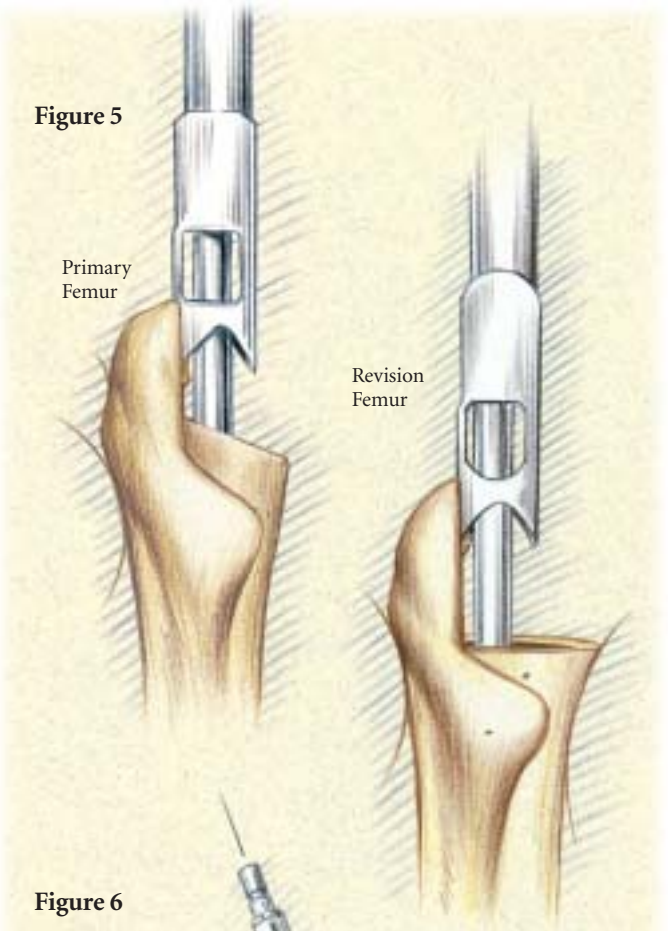
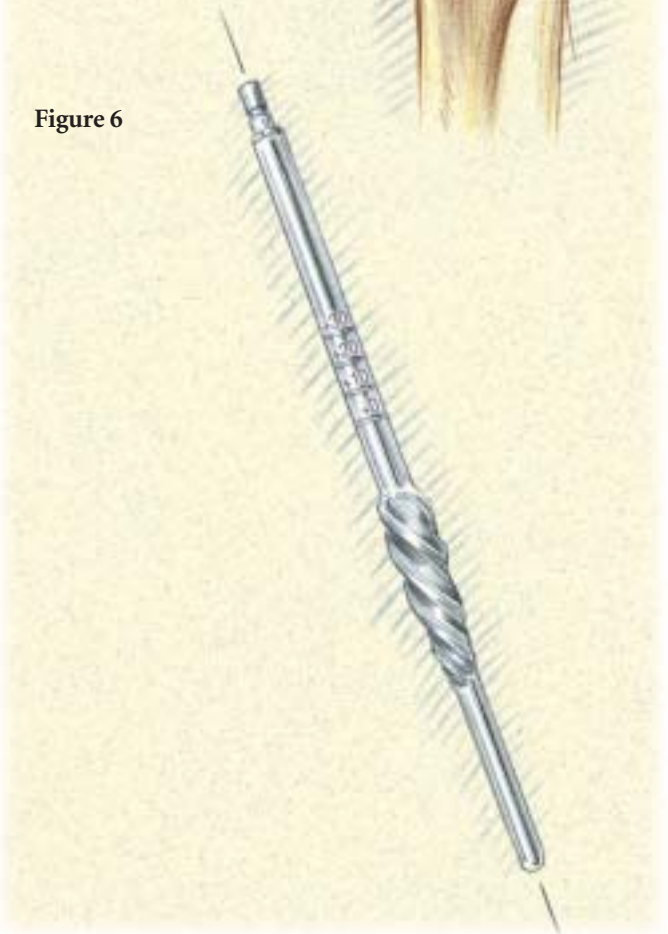
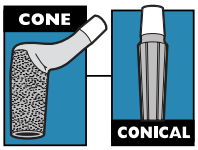


Figure 6





Distal Reaming

Use of the Conical Distal Reamer – 155mm, 195mm, 235mm Stems

Conical distal reaming for the 155mm, 195mm, or 235mm Conical Distal Stems can be accomplished by use of a T-Handle (**Figure 7**) or on power (**Figure 8**). Select the diameter of a Conical Distal Reamer starting with a size one or two millimeters smaller than the templated size. The reamer diameters are available in 1mm increments from 13mm - 28mm. There are three depth marking grooves on the shaft of the Conical Distal Reamers (225mm, 265mm, 305mm) which correspond to the distance from the tip of the greater trochanter to the tip of the 155mm Conical Distal Stem, 195mm Conical Distal Stem, or 235mm Conical Distal Stem, respectively (**Figures 9 and 10**).

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 155mm, 195mm, or 235mm Conical Distal Stem.

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 (225mm, 265mm, or 305mm) aligns with the tip of the greater trochanter, or other landmark as planned during preoperative templating (**Figure 10**).

Note: For the 155mm Conical Distal Stems, reaming to 225mm is recommended.

Note: For the 195mm Conical Distal Stems, reaming to 265mm is recommended.

Note: For the 235mm Conical Distal Stems, reaming to 305mm is recommended.

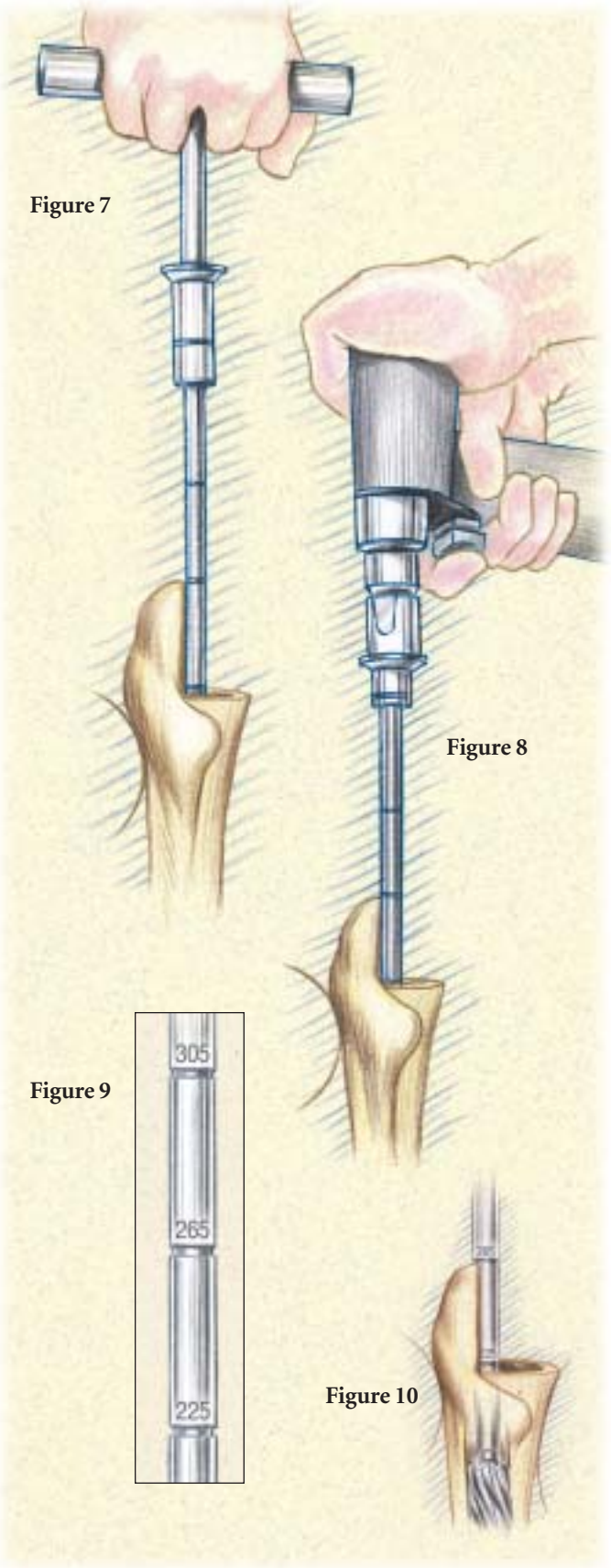


Figure 7

Figure 8

Figure 9

Figure 10

Distal Reaming (continued)/Implant Insertion

Use of the Conical Distal Reamer – 155mm, 195mm, 235mm 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 (**Figure 11**). It is important not to over-insert the Conical Distal Reamers as these are matched to a specific sized distal stem.

If good cortical contact is not achieved, increase the reamer diameter in 1mm increments and insert only as deep as the 225mm, 265mm, or 305mm 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 Conical Distal Reamers relative to the A/P and M/L femoral cortices and to the anterior bow of the femur.

Implant Insertion – Distal Stem

Thread the appropriate Conical Distal Stem onto the Distal Stem Inserter. The distal end of the inserter has a hex geometry with a spring-loaded threaded end that mates with a corresponding geometry on the stem. Make sure that the distal tip of the Distal Stem Inserter is correctly aligned with the hex orientation feature of the insertion hole of the implant (**Figure 12**). Fully and securely attach the instrument to the distal stem by turning the locking knob clockwise.

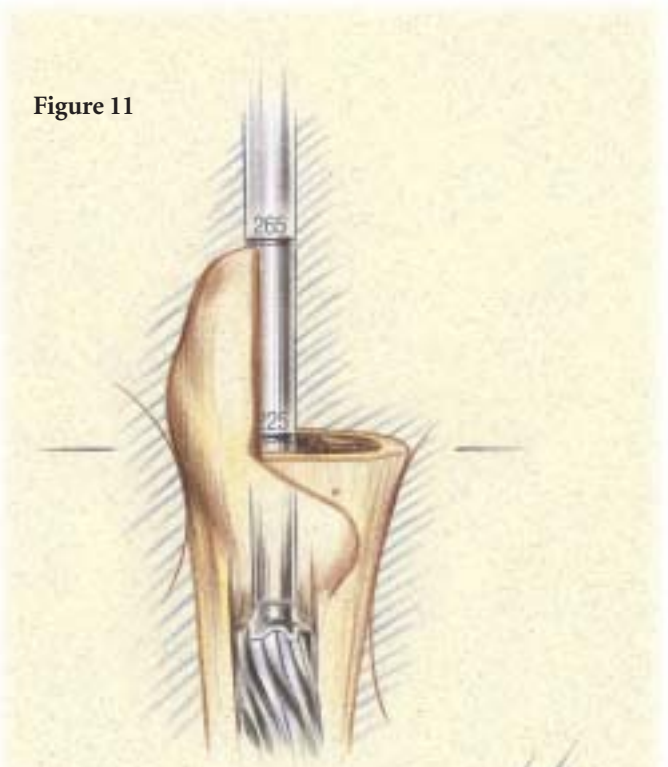


Figure 11

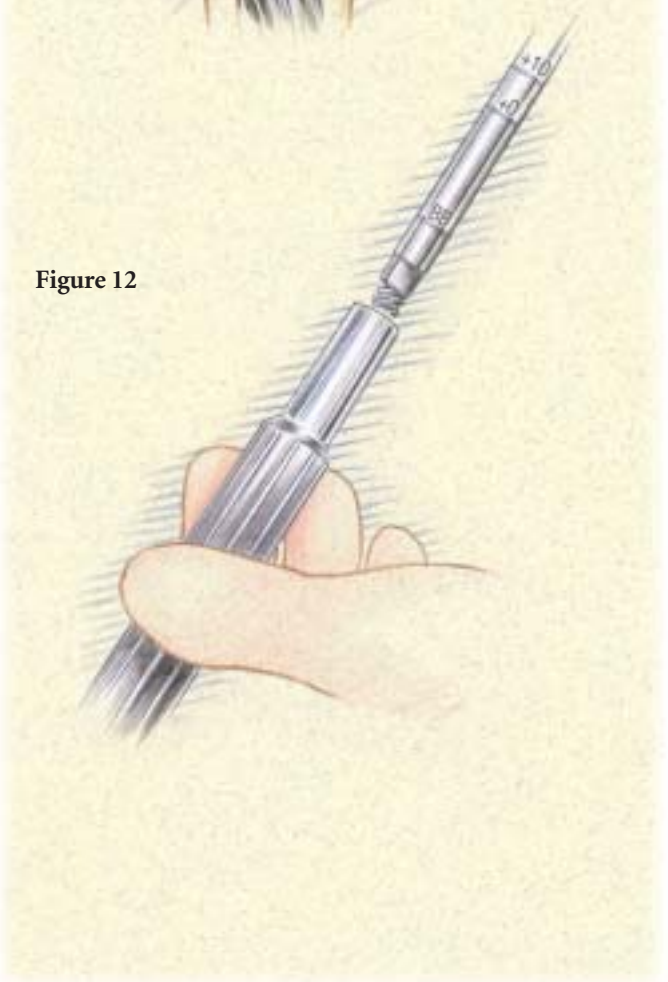
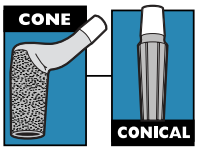


Figure 12



Implant Insertion – Distal Stem

Insert the Distal Stem

There are two options for inserting distal stems, the Version Control Stem Inserter (**Figure 13A**) and the Distal Stem Inserter (**Figure 13B**). Both inserters have four depth groove markings 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) (**Figure 13C**). 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 of satisfactory mechanical stability. Make sure that sufficient distal fixation is attained with all Conical Distal Stems, especially those that are significantly larger than the templated stem size.

Impact the Conical Distal Stem into the femoral canal until the stem will not advance any further, achieving rotational stability and preventing subsidence. View the depth groove on the stem inserter. These will align with the tip of the greater trochanter and will determine which body length will be used (+0mm (STD), +10mm, +20mm, or +30mm). 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 Conical Distal Stem may advance further into the canal than originally templated and reamed. The Cone Body is available in four heights to help restore the proper leg length. If the distal stem advances beyond the +30mm Proximal Cone Body level, ream up with the next size distal reamer and insert the corresponding distal diameter stem.

Remove the stem inserter by turning the locking knob counter-clockwise on top of the inserter.

Note: Depending on the bow of the femur, the trunnion of a *Straight Conical Distal Stem* may sit against the anterior femur upon insertion.

The *Bowed Conical Distal Stem* is designed to move the trunnion off the anterior cortex in the same type of femur (Figure 14).

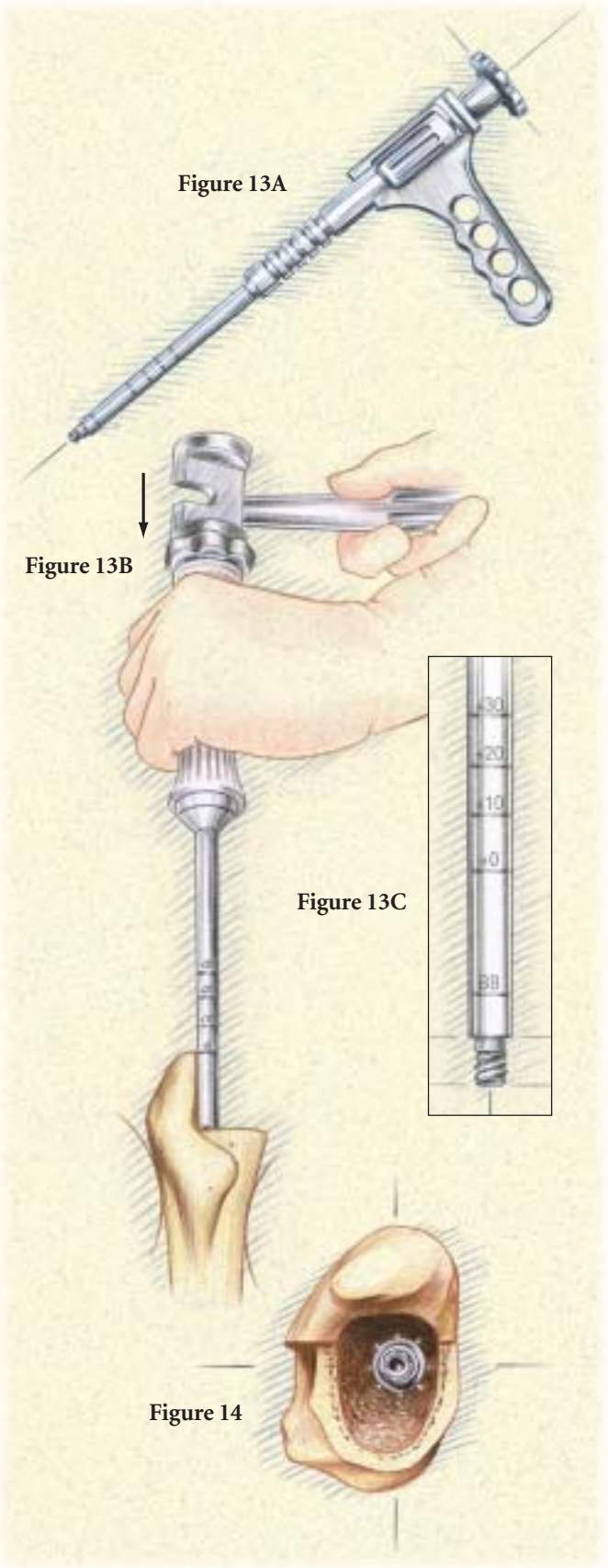


Figure 13A

Figure 13B

Figure 13C

Figure 14

Cone Body Preparation

The Cone Bodies are prepared by Proximal Cone Reamers which 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 (**Figure 15**).

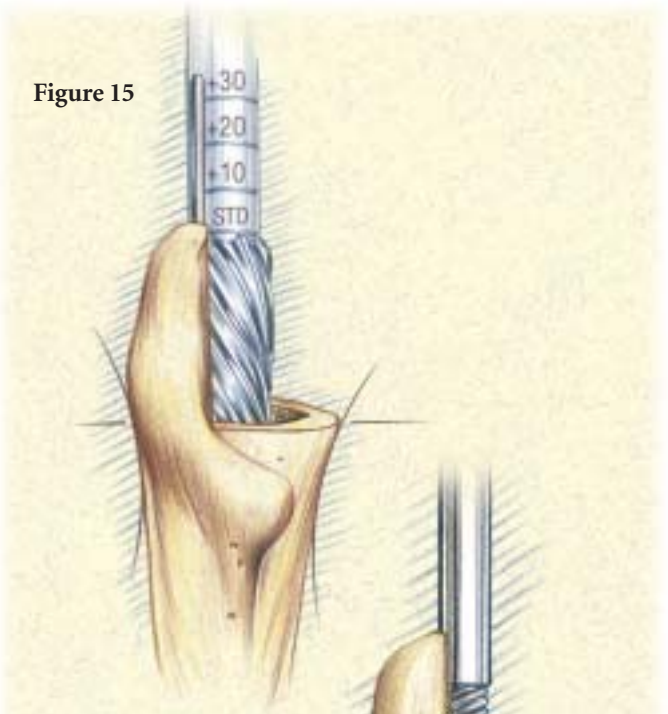


Figure 15

Insertion of Proximal Cone Reamer Guidepost

Remove the threaded Proximal Cone Reamer Guidepost from the tray and thread it into the top of the implanted Conical Distal Stem until fully seated. Use the 5mm Hex Driver and the small or large T-Handle to ensure full seating of the Guidepost on the distal stem; excessive torque is not required when tightening (**Figure 16**).

WARNING: Failure to fully seat the Proximal 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.

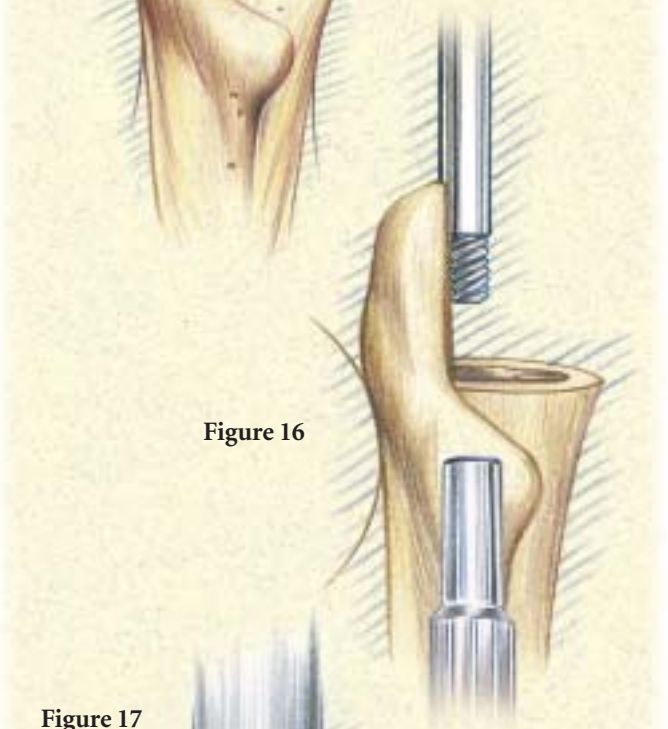


Figure 16

Proximal Cone Reaming

Starting with the 19mm Proximal Cone Reamer, commence proximal preparation for the Cone Body.

Attach the Proximal Cone Reamer to a power source and advance it over the Proximal Cone Reamer Guidepost until it bottoms out on the post and it is impossible to advance the reamer further - visualize this by looking at the alignment groove (on the Guidepost and reamer) or view the top of the proximal slot, which when fully seated, will show no gap between the reamer and the Guidepost (**Figure 17**).

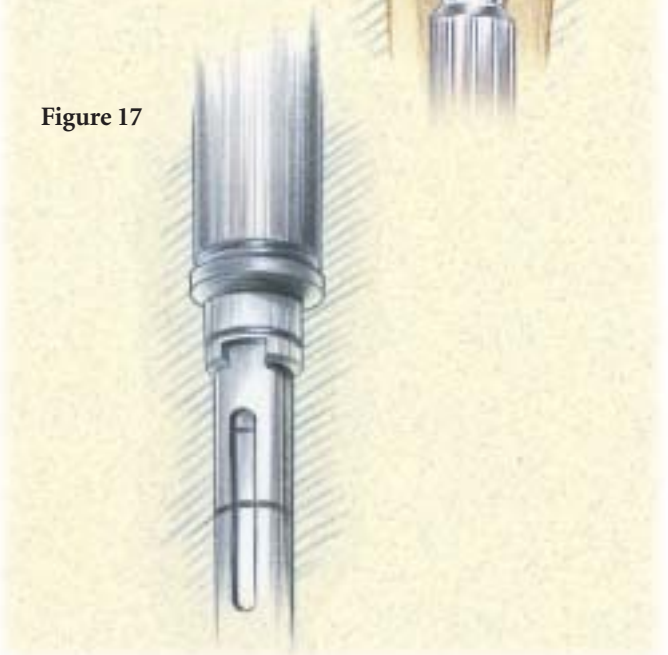
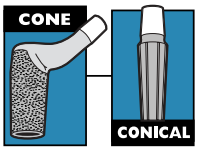


Figure 17

Proximal Cone reaming progresses in 2mm increments until satisfactory contact within the trochanteric region is felt. 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. If another landmark is used, note that the Proximal Cone Reamer grooves generally correspond with the femoral head center.

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



Cone Body Trial

Assemble the Appropriate Cone Body Trial to Conical Distal Stem

Select the Cone Body Trial corresponding to the final Proximal Cone Reamer diameter and proper height based on the reamer grooves. Assemble the 8mm Hex Locking Bolt Driver Shaft to the T-Handle (**Figure 18**). 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 locking bolt screwdriver assembly or the Distal Stem Inserter (**Figure 19**). Excessive torque is not required.

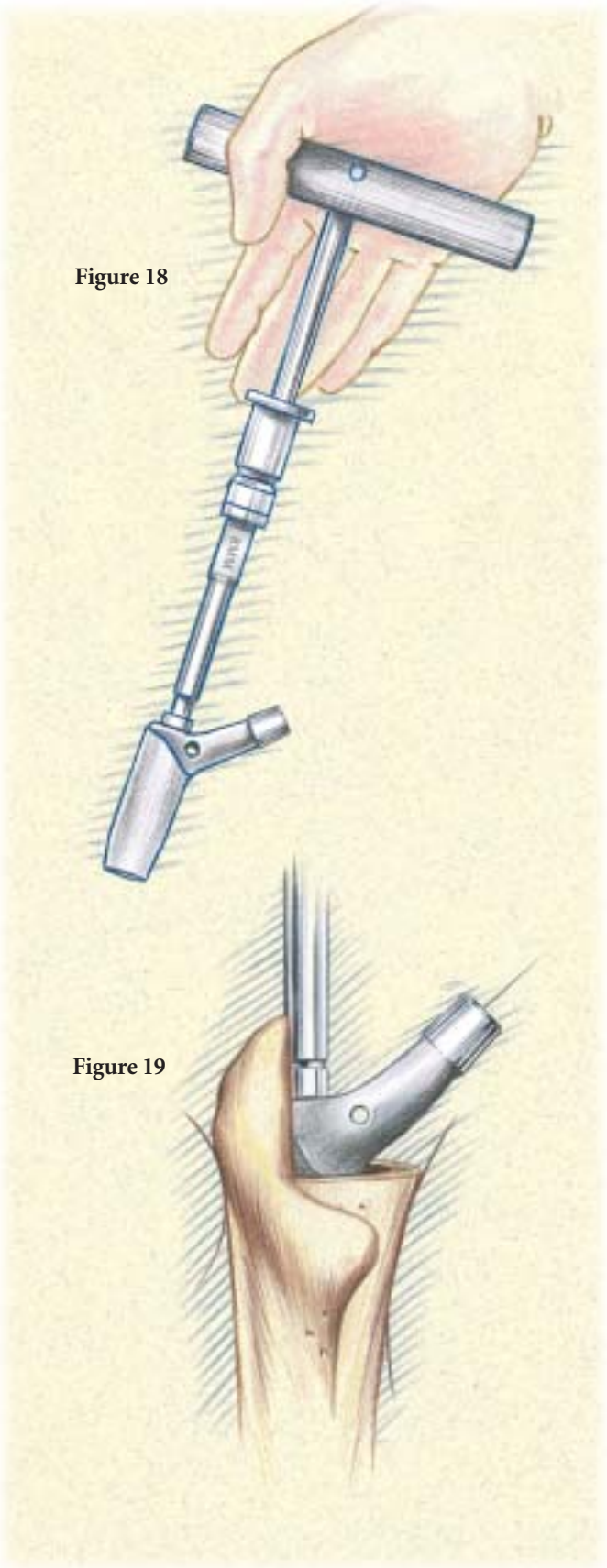


Figure 18

Figure 19

Cone Body Trial (continued)

Attach Trial Head

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 desired neck length based on preoperative templating from the chart below. Attach the Femoral Head Trial to the Cone Body Trial (**Figure 20**).

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.

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 bone with methylene blue or with a Bovie, 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 21).

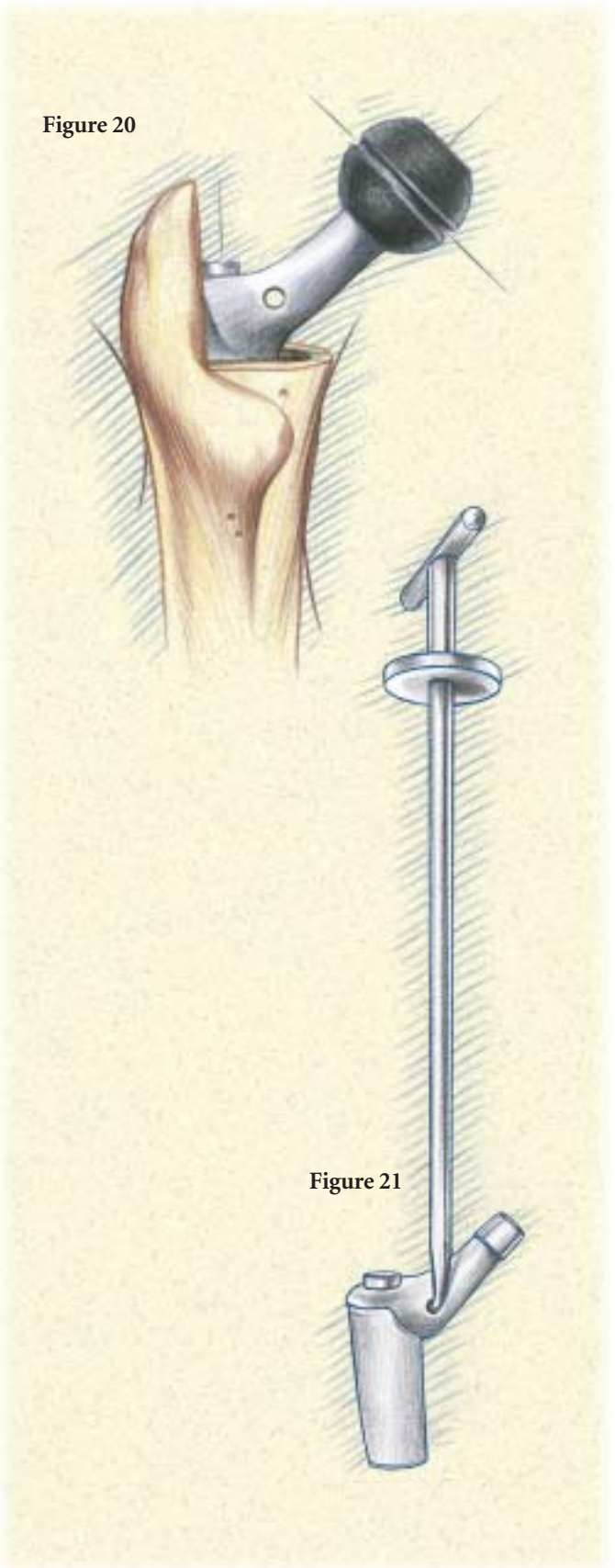
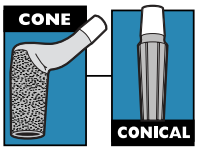


Figure 20

Figure 21



Cone Body Insertion/Taper Lock Gauge

Cone Body Impaction

Based on the trial reduction, select the appropriate height Cone Body implant. Lavage the area surrounding the proximal taper of the distal stem. Wipe the Conical 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 22**) and impact the Cone Body implant onto the trunnion of the Conical Distal Stem maintaining proper anteversion (**Figure 23**). The impaction of the Cone Body onto the trunnion of the distal stem cold-welds the tapers, locking the components together.

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 24**). Slide the handle down until it is fully seated in the proximal body (**Figure 25**). 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 26**).

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.

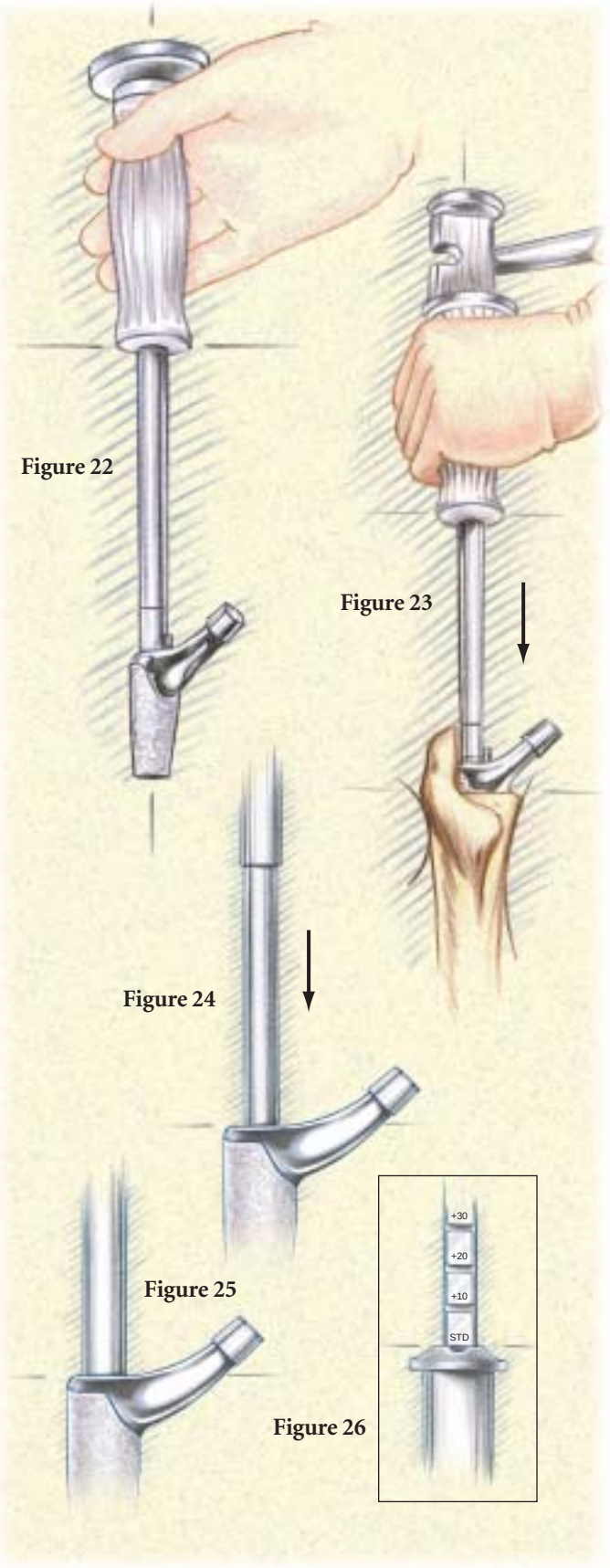


Figure 22

Figure 23

Figure 24

Figure 25

Figure 26

Locking Bolt Assembly and Tightening/Bone Grafting

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 27**). Assemble the Torque Wrench and Torque Wrench Adapter, and apply a minimum of 150in-lb and a maximum of 180in-lb torque to ensure that the Locking Bolt is sufficiently tightened (**Figure 28**). The Cone Body Steady Handle must be used to hold the anteversion of the Cone Body in place while applying torque. The Cone Body 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 29).

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 30).

Note: The Conical Distal Stems have Spiralock® threads that will not loosen if the Locking Bolt is sufficiently tightened. The Spiralock® 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.

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.

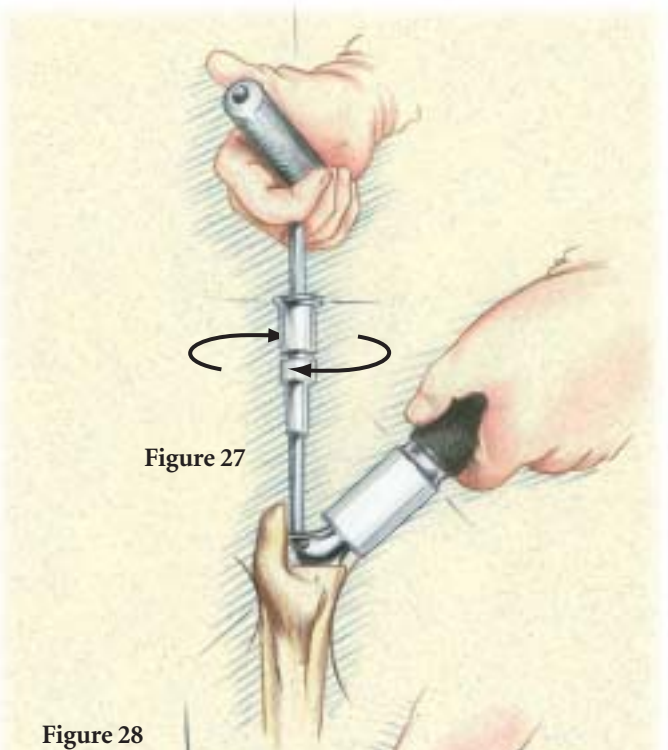


Figure 27

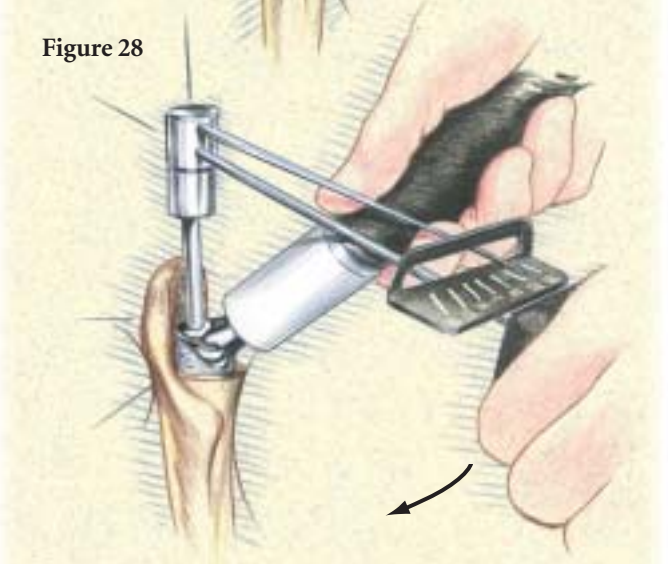


Figure 28

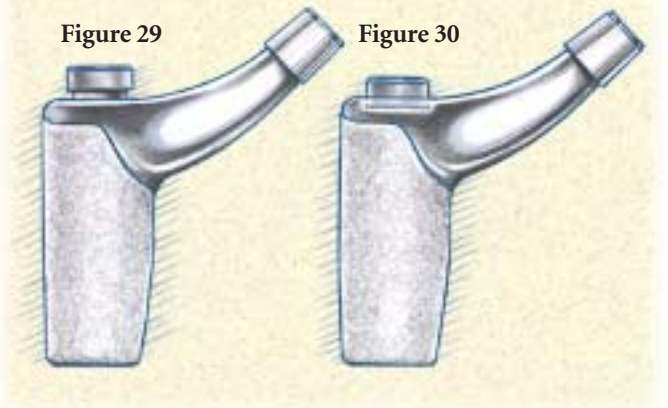
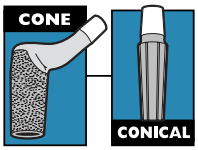


Figure 29

Figure 30



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 31**). 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 (**Figure 32 and 33**).

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.

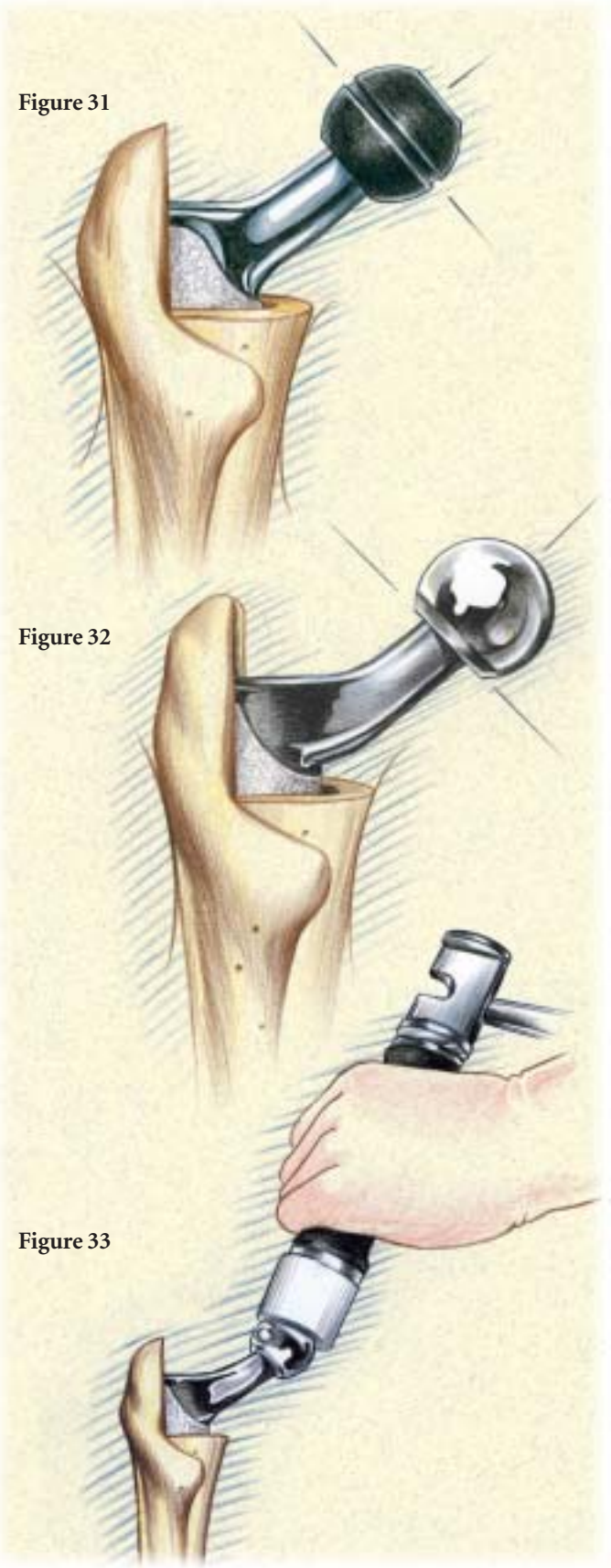


Figure 31

Figure 32

Figure 33

Restoration® Modular Cone Body/Conical 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 34).

Cone Body Removal

The Body/Stem Separator is made up of three parts: Jackscrew, Shaft Puller, and a reverse-thread Distal Collet (**Figure 35**). 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 36**).

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 35

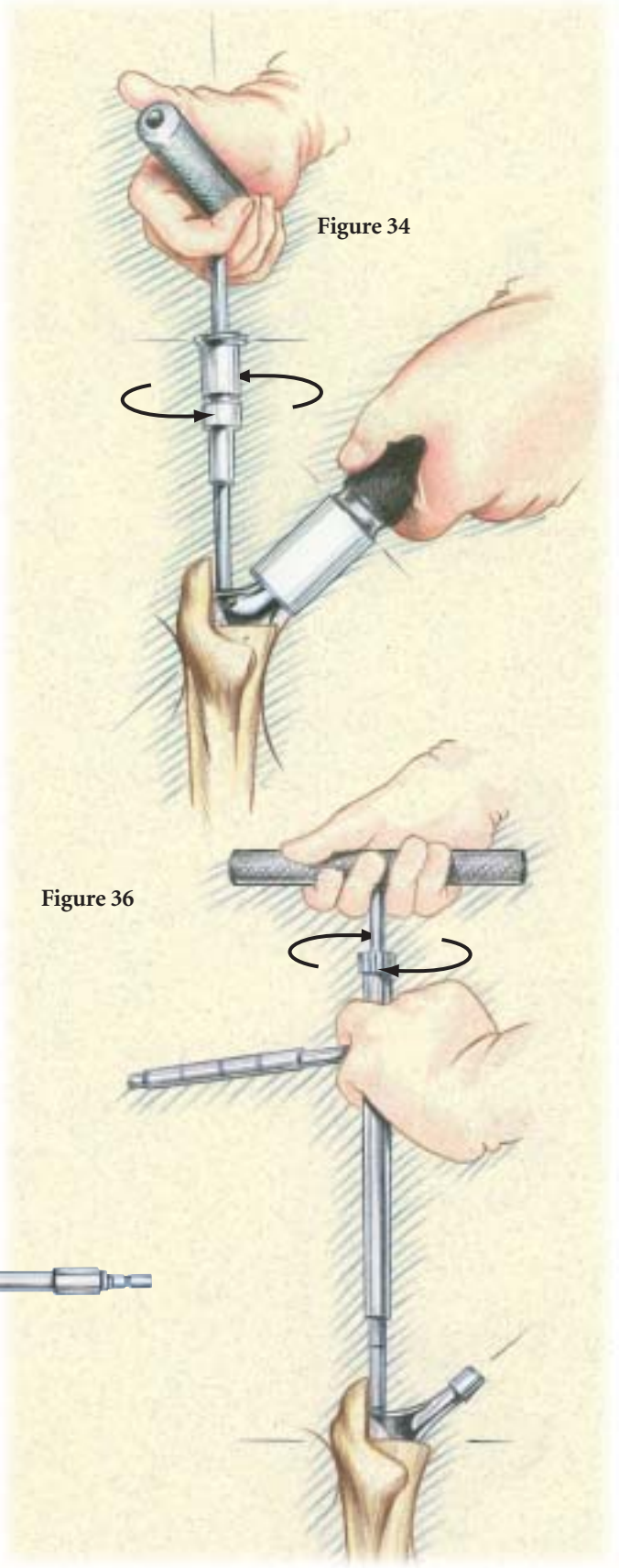
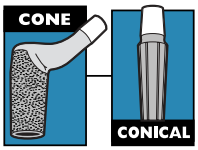


Figure 34

Figure 36



Restoration® Modular Cone Body/Conical 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 Conical Distal Stem (**Figure 37**). Use the slap hammer to remove the Conical Distal Stem from the canal.

Removal of the Restoration® Modular Cone Body/Conical Distal Stem Assembly

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 38 and 39**).

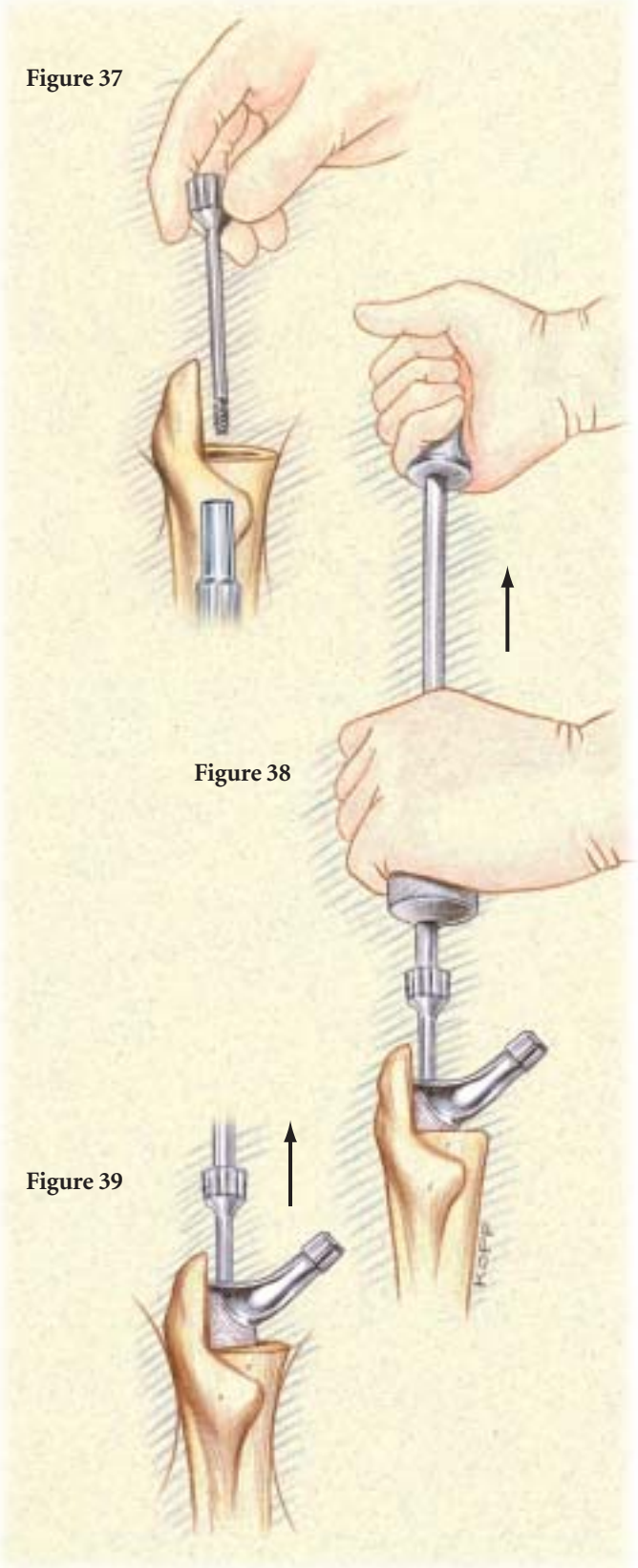


Figure 37

Figure 38

Figure 39

stryker®

Joint Replacements

Trauma

Spine

Micro Implants

Orthobiologics

Instruments

Interventional Pain

Navigation

Endoscopy

Communications

Imaging

Patient Handling Equipment

EMS Equipment

325 Corporate Drive
Mahwah, NJ 07430
t: 201 831 5000

www.stryker.com

Literature Number: **LRMCBC-ST Rev. 1**
TG/ITP 2.5M 6/05 8382