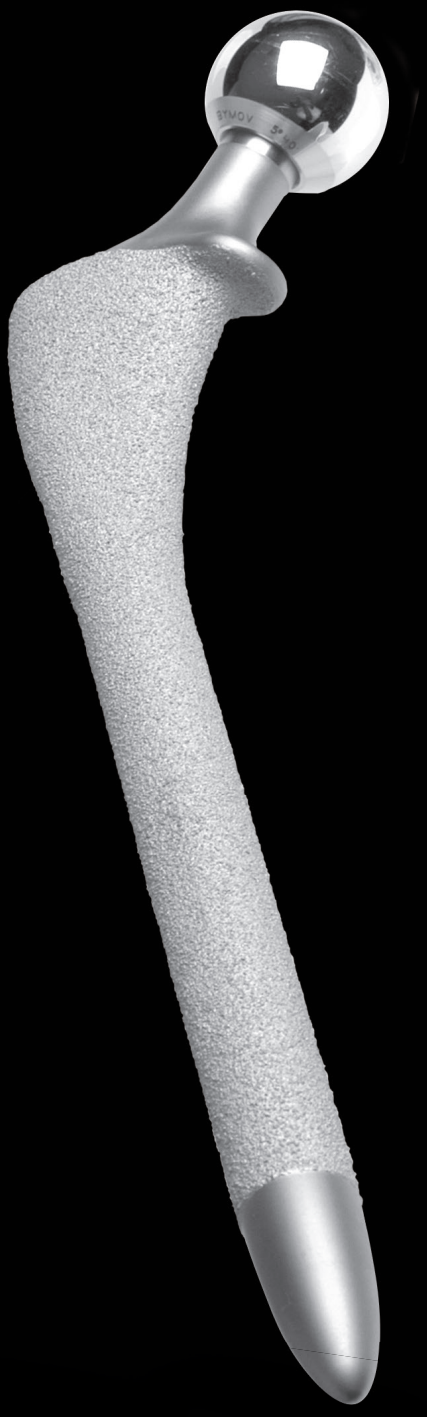
RESTORATION® PS

stryker®

REVISION HIP SYSTEM

Surgical Protocol



Restoration PS Femoral Component Using the Command Instrument System

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Surgical Technique

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Restoration PS System

The Partnership System is a collaboration between Stryker and a group of orthopaedic surgeons and biomedical design engineers. This team has developed an integrated series of implants and instruments designed to address the needs of patients, surgeons, and O.R. staff in today's changing healthcare environment. The design group includes:

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Indications

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

Contraindications

- Active infection or suspected latent infection in or about the hip joint;
- Bone stock that is inadequate for support or fixation of the prosthesis;
- Skeletal immaturity;
- Any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.

See package insert for warnings, precautions, adverse effects, information for patients and other essential product information.

Before using Restoration PS instrumentation, verify:

- Instruments have been properly disassembled prior to cleaning and sterilization;
- Instruments have been properly assembled post-sterilization;
- Instruments have maintained design integrity; and,
- Proper size configurations are available.

For instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices, refer to LSTPI-B

Preoperative Templating

The Restoration PS Hip System offers a complete set of femoral templates. All templates are at 20% magnification.

Acetabular Options

Stryker Orthopaedics offers a wide variety of acetabular components that are compatible with the Restoration PS Femoral Components. The surgeon should refer to a specific acetabular component's surgical technique for a discussion of acetabular surgical procedures. The Restoration PS Hip System is compatible only with Stryker Orthopaedics femoral bearing heads listed in the chart on page 16.

Surgical Approach

Each surgeon should use the surgical approach for total hip arthroplasty which 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 the proximal femur.

Preoperative Evaluation and Planning

Preoperative planning is essential in order to determine proper sizing and proper availability of implants. Preoperative templating helps the surgeon equalize leg lengths and calls attention to the possibility of more complex reconstructions, such as bone grafting. It is important that all preoperative x-rays are taken at a standardized distance, e.g. 44 inches. Keeping the beam at a standardized distance from the patient allows for a reproducible factor of magnification.

NOTE: All templates are at 20% magnification.

The figure to the right illustrates preoperative templating of a femoral component (Figure 1). First, the distal medullary canal is measured and the appropriate Restoration PS distal diameter is chosen. Template the distal canal line-to-line or allow for 1mm to 2mm of further reaming. Then, choose the appropriate Restoration PS proximal body size that will adequately fill the proximal femur on both the A/P and lateral projections. Since primary fixation is achieved in the medullary canal, proximal sizing need not be overly large.

The unique geometry of the Restoration PS stem allows for a distal cylindrical fit, a short middle proximal cone, and a rectangular proximal body.

Leg lengths are equalized by templating the acetabulum and locating the center of the femoral head, then adjusting the superior and inferior position of the Restoration PS stem to restore the proper correction. The proper level of femoral neck osteotomy is marked and noted for surgery.

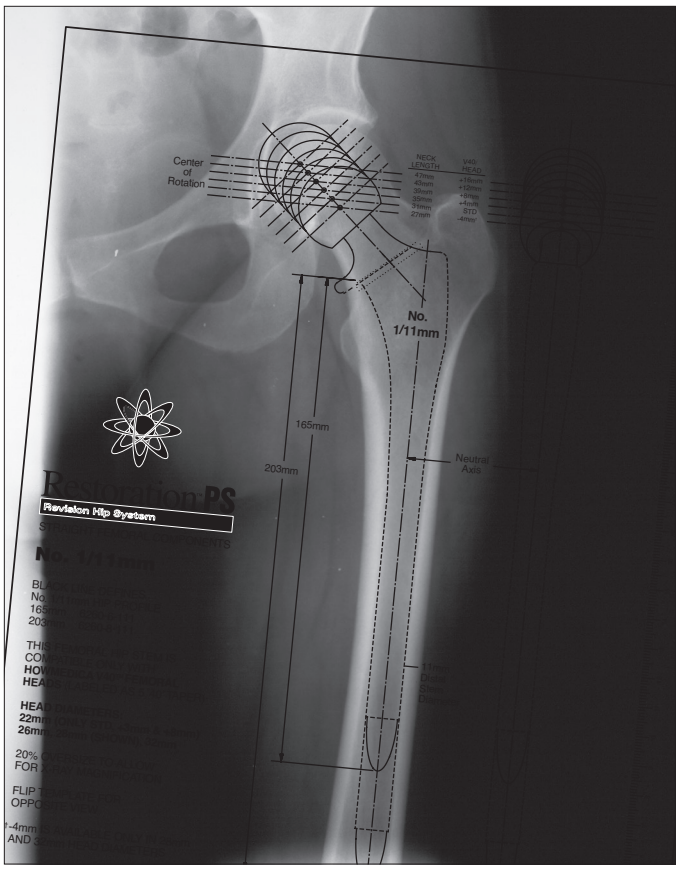


Figure 1

Starting Options

Determine and Mark the Osteotomy Level

By using anatomic landmarks identified during the preoperative templating, the osteotomy guide assists the surgeon in identifying the location of the osteotomy cut. The resection level should be identical to the level chosen during preoperative templating.

The osteotomy guide consists of one angled osteotomy body/handle and a series of osteotomy attachments. An axial alignment rod along with the osteotomy attachments will lock into the osteotomy body.

The osteotomy guide has several features to assist the surgeon:

Option 1

A Long tail of the osteotomy guide for alignment with the femoral shaft axis.

B Notch in the proximal portion of the guide references the proximal tip of the greater trochanter.

C Location holes determine the center of rotation for head position options available for stem size.

Care must be taken to restore proper leg length and soft tissue tension by referencing the femoral neck osteotomy level to the center of rotation of the implanted acetabular component. This often results in a resection level of about one fingerbreadth above the lesser trochanter. The angled surface provides a plane for marking the level of the cut, or it can be used as a cutting surface for the sawblade. Do not use the slot in Option 2 as a cutting guide. Use the angled surface only for proper osteotomy level.

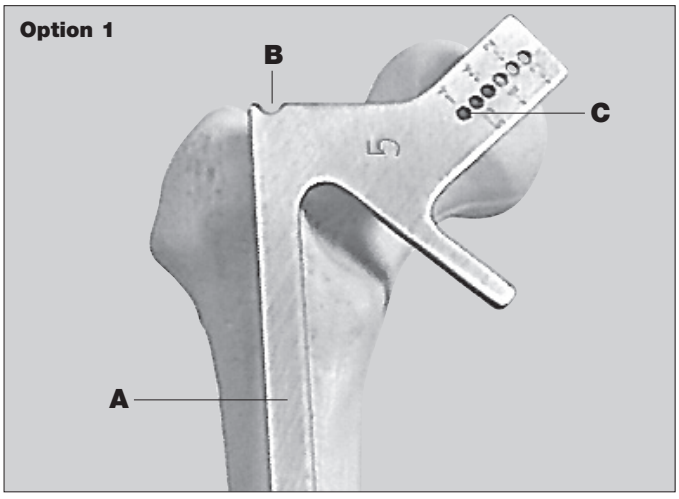
The osteotomy may be made in neutral alignment or in slight anteversion, depending upon surgeon preference. The reference for the version of the osteotomy should be the transverse axis of the knee or the long axis of the tibia, depending on the surgical approach used.

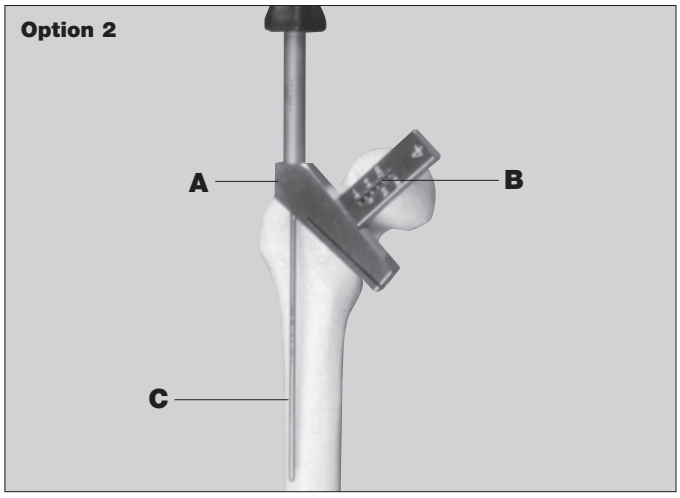
Option 2

A The osteotomy body is designed to accommodate the osteotomy levels of the standard Partnership stems.

B The modular osteotomy attachments are size-specific for each stem, and feature "head-center" holes that indicate each neck length option available with that stem.

C A removable axial alignment rod fits into the osteotomy body, and is used by the surgeon to indicate proper femoral long axis alignment.





Perform Osteotomy

Make a 40° osteotomy angle cut which often eliminates the need for a second cut to complete resection (Figure 2). However, if the lateral extension of the neck osteotomy endangers the trochanteric bed, then a second osteotomy should be made with an oscillating saw or a sharp osteotome in the vertical direction.

Figure 2

Open and Size the Canal with Starter Awl

The tapered starter awl is a hand-operated instrument, designed to open the femoral canal and estimate the distal diameter size. Assemble the small hex T-handle onto the starter/sizer awl, and target the piriformis fossa to open the canal. The starter/sizer 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 3).

Progress the awl distally using progressively larger awls until some cortical resistance is achieved. Use the aggressive cutting teeth of the starter awl to achieve lateralization.

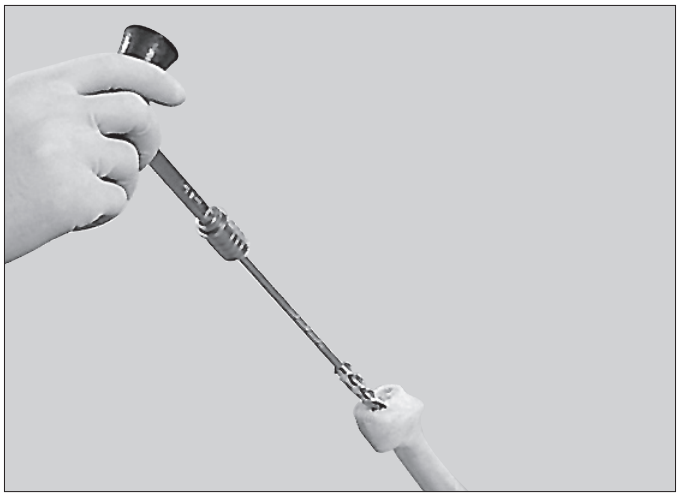


Figure 3

Depth of Starter Awl

Make note of the millimeter diameter marking that appears at the calcar osteotomy level. The marking grooves on the shaft identify distal diameter sizing of the femoral canal (Figure 4).

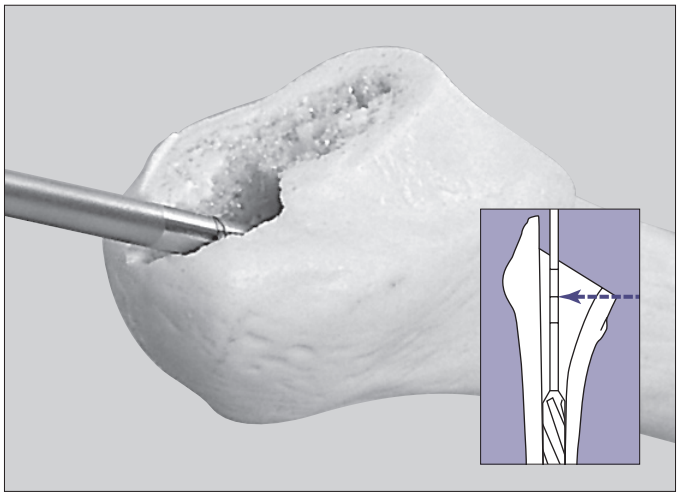


Figure 4

Reaming

Assemble and Introduce Straight IM Reamer

Assemble a power adaptor to the straight, cylindrical IM reamer (Figure 5). Select the diameter of the reamer based on the last starter awl diameter reading, starting with a size one or two millimeters smaller.

CAUTION: Do not exceed the diameter of the anticipated implant size as indicated on preoperative templates.

Use of the Straight IM Reamer and Depth Markings

Ensure that the reamer provides lateralization and is directed in a neutral position. Care must be taken during reaming to avoid thinning the anterior or posterior cortex eccentrically (Figure 6).

NOTE: When lateralizing rigid reamers, take care to properly retract/protect the abductor muscle fibers of the gluteus minimus/medius at the superior tip of the greater trochanter.

Insert the straight IM reamer until the proximal teeth of the reamer have gone beyond the medial edge of the calcar osteotomy.

NOTE: Achieving the proper depth of the reamer is essential to ensure that the implant can be fully seated on the medial calcar.

Progressively ream until the desired distal diameter is reached. The final reaming size is left to the surgeon's discretion. The surgeon may wish to consider line-to-line reaming in cases where the patient's cortical bone is extremely hard or scratch fit (under-reamed by 0.5mm) in softer bone. Proper medullary reaming is completed when cortical "chatter" is achieved for at least 3cm to 4cm in the distal medullary canal to the appropriate depth.

In order to under-ream by 0.5mm, stop reaming with the straight IM reamers that are available in whole millimeter increments only, at least 1mm below the desired implant size, and proceed with the Restoration PS distal reamers, which are available in half millimeter increments.

NOTE: In most cases, line-to-line reaming is satisfactory.

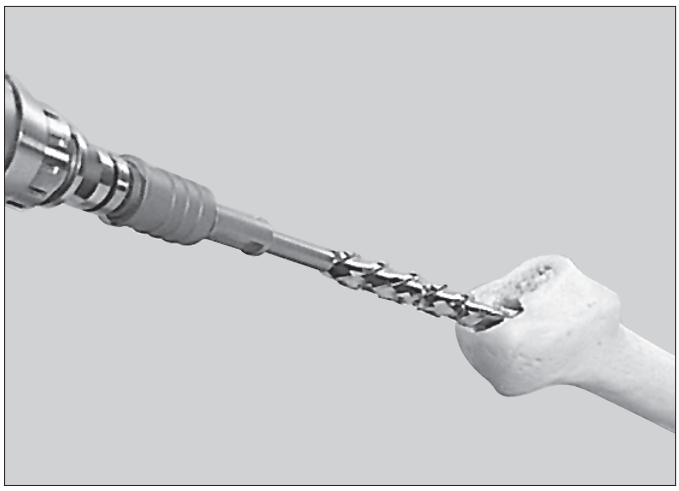


Figure 5

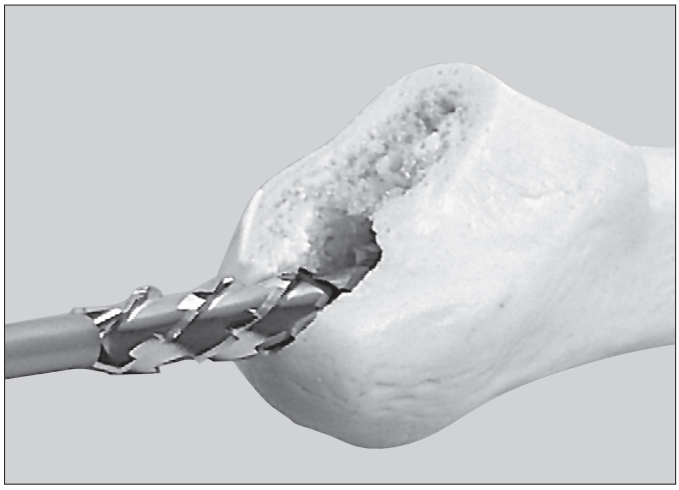


Figure 6

Assemble and Introduce the Restoration PS Distal Reamer

Choose the appropriate Restoration PS distal reamer, equal to the diameter of the last straight IM reamer used, and assemble to the small hex power adaptor, or small hex T-handle, if preferred. Progressively ream until the proper distal diameter is reached (Figure 7).

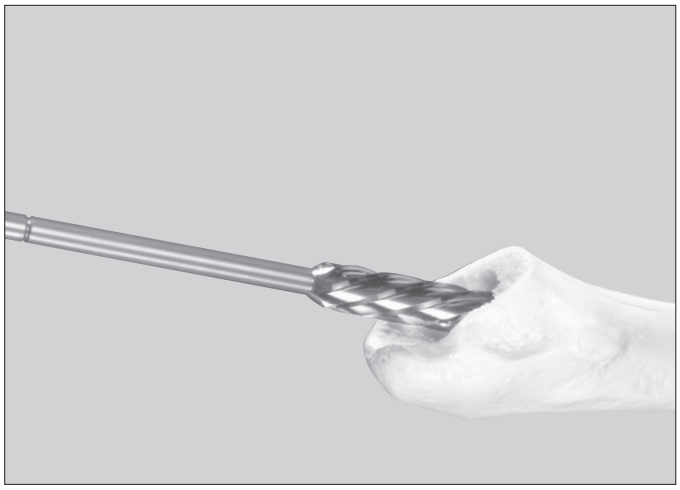


Figure 7

Assemble the Restoration PS Proximal Sleeve Reamer

Assemble the appropriate Restoration PS proximal sleeve reamer, determined during templating and confirmed during surgery, over the Restoration PS distal reamer (Figure 8).

The Restoration PS proximal sleeve reamer is double-ended; thus, the sleeve must be assembled in the correct orientation. The sleeves are marked with arrows pointing in the direction of assembly for either the 165mm or the 203mm stem lengths.

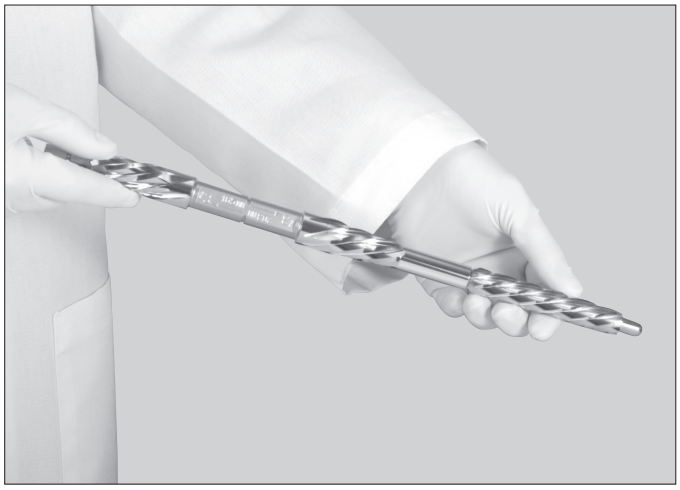


Figure 8

Use of the Restoration PS Distal Reamer/Proximal Sleeve Reamer Depth Markings

Insert the distal reamer/proximal sleeve reamer assembly into the canal (Figure 9) and **ream until the center depth-groove marking (see inset in figure 9) is completely below the medial side of the calcar osteotomy.**

NOTE: Achieving the proper depth of the reamer is essential to allow that the implant may be fully seated on the medial calcar.

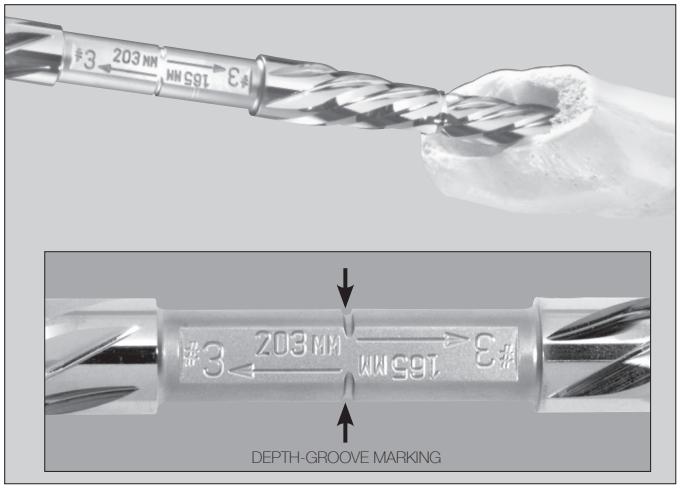


Figure 9

Broaching

Assemble Modular Distal Tip to Broach

Select a broach one or two sizes smaller than the anticipated implant size. Select the modular distal tip that corresponds to the distal diameter of the last reamer used. Assemble the modular distal tip to the broach by threading the tip tightly onto the end of the broach, using the pin wrench, if necessary (Figure 10). The accurately sized modular bullet tip engages the axis that you have reamed, providing for neutral placement of the broach.

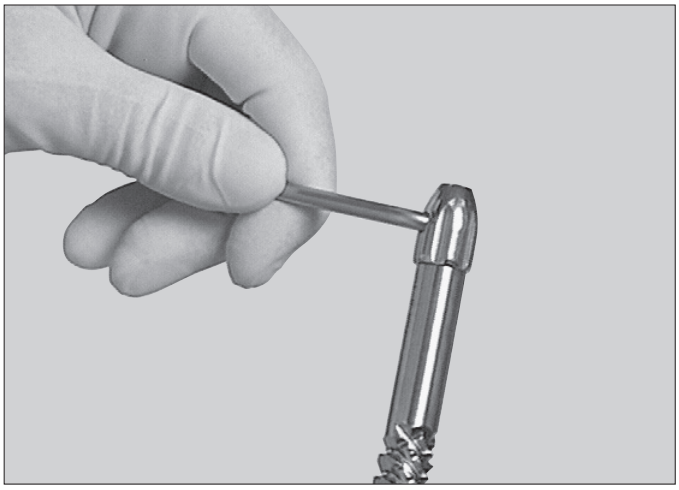


Figure 10

Assemble Broach Handle to Broach

Assemble the broach handle to the broach. Make sure that the tip of the broach handle is correctly mated with the keyway on the broach. Turn cam in "lock" direction until audible clicks are heard and the broach is securely attached (Figure 11). Final tightening can be accomplished with a "Tommy Bar" or clamp.

Figure 11

Broaching and Trial Reduction

Introduce the Broach

Initial broaching is undertaken with a broach that is one or two sizes below the anticipated final size. Introduce the broach into the proximal femur, protecting the abductor muscle mass (Figure 12). Drive the broach down the canal with a heavy mallet, using firm, short, sharp taps rather than long hard ones. Keep the broach aligned with the neutral femoral axis. If the broach does not advance, it must be removed and re-directed.

Once the smaller size broach is buried beneath the edge of the calcar, the next size broach should be impacted. Assess the fit and resistance to movement. If a larger size is needed, remove the broach and replace it with the next size. To facilitate the final seating of the broach, partially withdraw the broach to clear the cutting teeth of bone; then re-introduce the instrument into the canal with the mallet.

NOTE: If a broach larger than the size templated is to be used, it may be necessary to ream the canal up to the appropriate diameter. Since fixation is to be obtained distally, the proximal portion does not need to be as tight as required for implants designed for proximal fixation.

If bone stock is compromised or very thin, the surgeon may elect to prophylactically wire the femoral shaft with cerclage wires or Dall-Miles cables to secure the proximal femur and help prevent fracture.

When the proper size broach is fully inserted at the level of the calcar, a trial reduction using trial necks and heads should be carried out to assess stability and leg length.

NOTE: The final broach is countersunk 1mm to verify full seating of the collar.

Calcar Planer

Leave the final broach fully seated or slightly below the cut surface of the femoral neck. Remove the broach handle. The broach trunnion may be used as a guide for the calcar planer. The calcar planers come in two sizes: standard and large. Select the appropriate size planer and assemble to the power adaptor. The female bushing on the planer is guided over the broach trunnion (Figure 13). The abductor mechanism and the greater trochanter must be protected. **The calcar planer creates a smooth surface on which the Restoration PS medial collar may be fully seated, aiding in load transfer.**

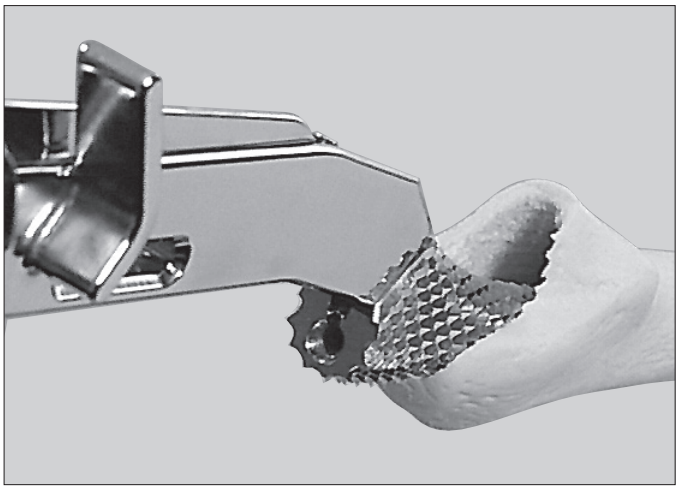


Figure 12

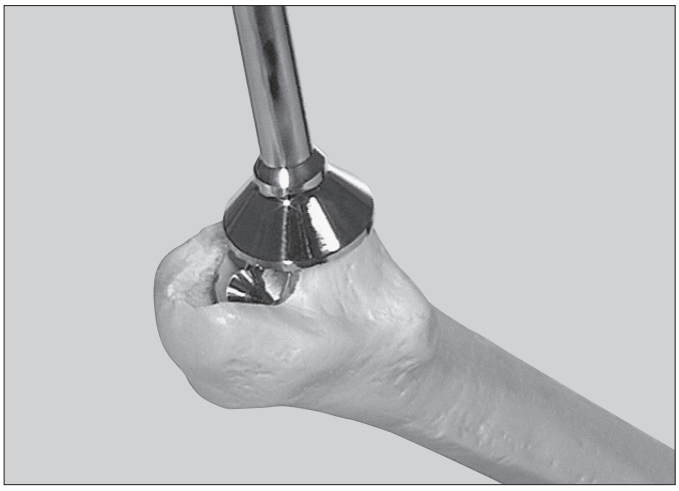


Figure 13

Broaching and Trial Reduction (continued)

Fit the Neck Trial to the Broach

Select the appropriate size neck trial/collar trial corresponding to the broach/implant size, and fit the neck trial/collar trial securely onto the broach (Figure 14).

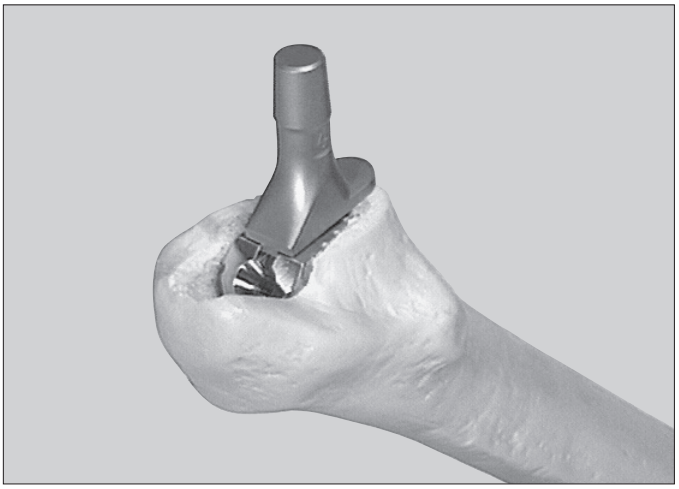


Figure 14

Attach Head Trial

Select the head diameter [22mm, 26mm, 28mm, 32mm, 36mm, 40mm or 44mm according to surgeon preference. The head trials have a circumferential groove, which identifies the level of the center of rotation. Select the appropriate neck length: -4mm, +0mm (STD), +4mm, +8mm, +12mm based on preoperative templating (Figure 15). (Offset may be increased by cutting the neck shorter and using a longer neck length.) Attach the head trial to the neck trial and perform a trial reduction, assessing the hip for stability, telescoping, leg length, and overall range of motion. Remove the broach and all trials.

NOTE: -4mm neck length is not available in 22mm, 26mm or 36mm head sizes. Refer to sizing chart on page 16.

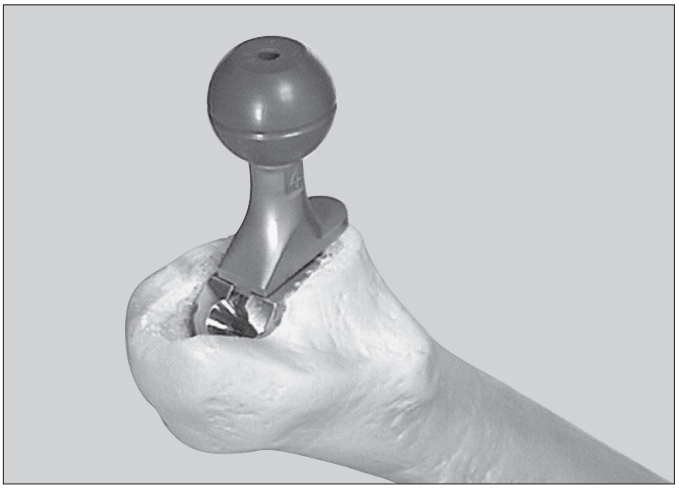


Figure 15

STEM INSERTION

Assemble Introducer to Implant

Assemble the insertion tool to the implant. Make sure that the distal tip of the instrument is correctly aligned with the orientation keyway of the insertion feature of the implant. For ease of assembly, hold instrument as illustrated (Figure 16) using the thumb to turn the grooved knob. Fully secure instrument to implant with the locking knob on top of the stem inserter.

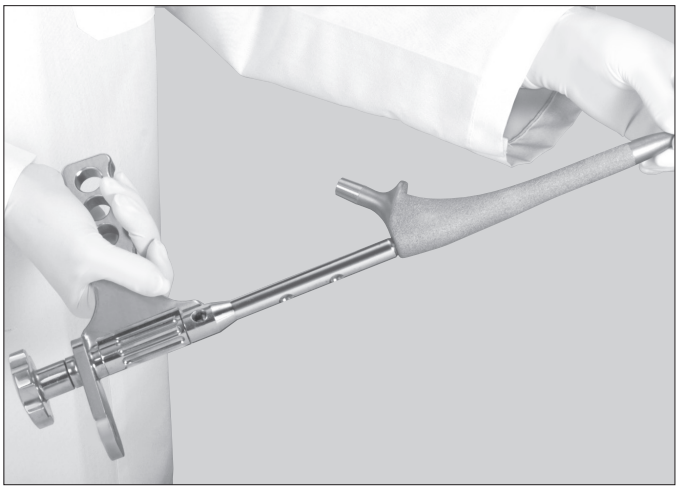


Figure 16

Stem Insertion (continued)

Insert the Implant

Insert the implant firmly into the femoral canal by hand, using the handle of the introducer to control and reference anteversion. The prosthesis should come to rest no more than 3cm from the medial edge of the osteotomy.

If the distance from the medial collar of the prosthesis to the medial osteotomy is more than 3cm, then the femoral canal should be checked to ensure that it was reamed to the proper depth and that the prosthesis was positioned correctly. Complications that may arise with impaction of an implant that is more than 3cm proud include: proximal femoral fracture, a stem that cannot be seated on the medial calcar, and the inability to remove the stem.

Impact the Restoration PS Femoral Component with sharp, short blows using a heavy mallet (Figure 17).

As in broaching, cerclage wires or Dall-Miles cables and sleeves, may be used to prophylactically protect the proximal femur from fracturing during impaction. This method may be especially helpful if the residual cortical bone is thin.

Impact the prosthesis until the medial collar seats on the osteotomy surface. If the prosthesis will not seat completely but is stable to all movement, the surgeon may elect to leave the prosthesis "proud," which will eliminate the load-sharing characteristics of the medial collar. Adjustments in neck length must be made accordingly. While cosmetically unappealing, because the collar is small, there is no functional downside to leaving it slightly proud. If the implant will not completely seat, check for proper positioning and any impinging osteophytes or residual neck bone. The surgeon may also elect to ream up another 0.5mm, then try impaction again.

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

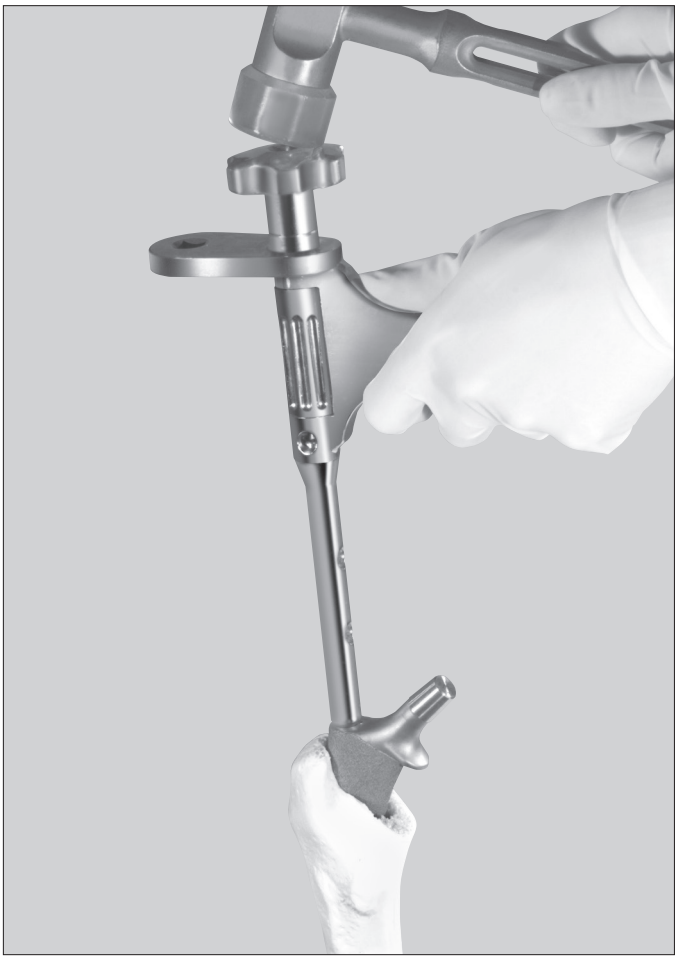


Figure 17

Completion

Final Trial Reduction

A femoral head trial may be placed on the implant and a final trial reduction performed (Figure 18). Prior to the trial reduction, it is important to remove all retractors, which can provide a false sense of stability. If excess telescoping exists, a longer neck length may be necessary.

The key to stability is restoring the myo-fascial tension.

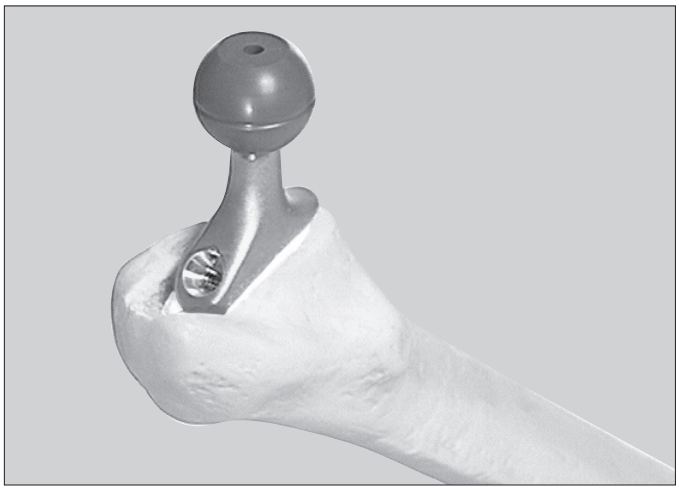


Figure 18

Impact Head onto Stem

Select the appropriate size Stryker Femoral Head, wipe the trunnion clean, and impact the head on the trunnion with the femoral head impactor (Figure 19). Impaction of the femoral head should be in line with the trunnion rather than the line of the femoral stem.

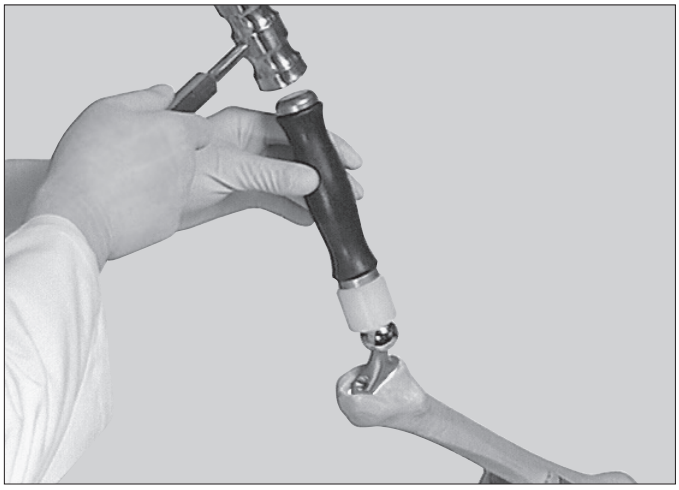


Figure 19

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 surgeon's choice.

Revision Technique

When a patient comes to revision surgery, there is often significant bone loss, which must be addressed in order to obtain a stable, long lasting revision construct.

The basic principle of uncemented revision surgery using extensively coated stems is to achieve diaphyseal fixation. This is usually out of necessity since the proximal region and metaphysis of the femur are often devoid of good quality and quantity of host bone. Therefore, fixation can be achieved distally by a tight scratch fit, and proximal fill is provided by the implant and supplemental bone graft, if necessary. Unless the implant is rotationally stable, success can not be achieved.

A Type 1 defect, having only minor bone loss, is easily handled. Since the diaphysis is intact, a good distal fit can be obtained. Since there is minimal bone loss anteriorly and posteriorly, a proximal fill can be achieved with good stability in most cases.

In Type 2 defects, there is more significant bone loss, the metaphysis is compromised and often there is loss of calcar. In these cases, the diaphysis is intact, and therefore, diaphyseal fixation can be achieved. However, since the calcar is deficient or absent, either a calcar replacement head neck stem must be used or bone graft must be considered, either particulate or bulk. With long defects, strut grafting should be considered over the implanted stem securing the graft with Dall-Miles cables.

In Type 3 cases, with massive bone loss, the surgeon is dealing with very poor host bone. If possible, some normal diaphysis should be found distal in the shaft. In these cases, proximal bone loss must also be supplemented with particulate graft, bulk allograft, or strut grafting techniques to best achieve a stable construct.

Stem Removal

Any extensively coated stem designed for cementless fixation can be difficult to remove if not loose. All standard measures, including the use of appropriately extensile exposures, such as a trochanteric osteotomy, extended trochanteric osteotomy and even a cortical fenestration should be used to remove the stem, if necessary due to infection or other complications. The surgeon must divide the interface between the host bone and the fixed implant, preserving as much bone as possible with small flexible osteotomes or small power burrs.

Special techniques may be required in cases when it is very difficult to break the bond far below the available surface.

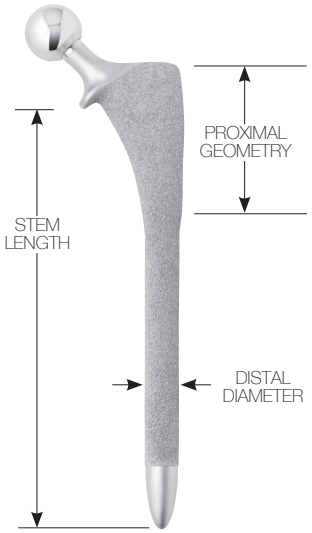
Trephine Technique

Using the Trephine technique, a cortical window is made on the anterior or anterolateral surface of the femur at the level where the cylindrical portion of the Restoration PS stem joins the middle conical portion. The cortical window is removed and saved for later re-implantation.

Transect the Restoration PS titanium stem using a Midas Rex or similar high-speed tool. Once the proximal body is transected, the proximal portion may be removed using thin osteotomes and thin motorized burrs. Extract the proximal portion of the stem, leaving just the cylindrical distal stem fixed in the bone.

Remove the distal stem using disposable trephines that are 0.5mm larger than the implant *in-situ*. Usually, once the stem is trephined completely to its distal portion, the stem will come out with the trephine. If the stem does not come out with the trephine, a distal cortical window, on the anterolateral side, could be made to tap the prosthesis out from below.

Implant Name	Proximal Geometry	Distal Diameter	Neck Length with a Standard Head	Neck Angle	165mm Straight Stem Length	203mm Straight Stem Length
#1/11mm	#1	11mm	31mm	132°	165mm	203mm
#2/12mm	#2	12mm	32mm			
#1/13mm	#1	13mm	31mm			
#3/13mm	#3	13mm	34mm			
#2/14mm	#2	14mm	32mm			
#4/14mm	#4	14mm	35mm			
#3/15mm	#3	15mm	34mm			
#5/15mm	#5	15mm	37mm			
#4/16mm	#4	16mm	35mm			
#6/16mm	#6	16mm	37mm			
#5/17mm	#5	17mm	37mm			
#7/17mm	#7	17mm	37mm			
#6/18mm	#6	18mm	37mm			
#8/18mm	#8	18mm	42mm			
#7/19mm	#7	19mm	39mm			
#8/20mm	#8	20mm	42mm			
#9/21mm	#9	21mm	42mm			



Neck Length†

Stem Size	-4mm	+0mm (STD)	+4mm	+8mm	+12mm
#1	27mm	31mm	35mm	39mm	43mm
#2	28mm	32mm	36mm	40mm	44mm
#3	30mm	34mm	38mm	42mm	46mm
#4	31mm	35mm	39mm	43mm	47mm
#5	33mm	37mm	41mm	45mm	49mm
#6	33mm	37mm	41mm	45mm	49mm
#7	35mm	39mm	43mm	47mm	51mm
#8	38mm	42mm	46mm	50mm	54mm
#9	38mm	42mm	46mm	50mm	54mm

Femoral Head Offset† (V40 Femoral Heads)

Stem Size	-4mm	+0mm (STD)	+4mm	+8mm	+12mm
#1	31mm	34mm	37mm	40mm	43mm
#2	33mm	36mm	39mm	42mm	45mm
#3	37mm	40mm	43mm	46mm	49mm
#4	41mm	44mm	47mm	50mm	53mm
#5	44mm	47mm	50mm	53mm	56mm
#6	47mm	50mm	53mm	56mm	59mm
#7	49mm	52mm	55mm	58mm	61mm
#8	52mm	55mm	58mm	61mm	64mm
#9	52mm	55mm	58mm	61mm	64mm

† Please refer to Femoral Head Compatibility Chart below for options available.

Femoral Head Compatibility

Head	Head Size	Head Offsets
CoCr V40	22	+0, +3, +8
	26	-3, +0, +4, +8, +12
	28	-4, +0, +4, +8, +12
	32	-4, +0, +4, +8, +12
	36	-5, +0, +5, +10
	40	-4, +0, +4, +8, +12
	44	-4, +0, +4, +8, +12
Alumina V40	28	-2.7, +0, +4
	32	-4, +0, +4
	36	-5, +0, +5
Alumina C-Taper (when used with C-Taper Adaptor Sleeve-catalog #17-0000E)	28	-2.5, +0, +5
	32	-2.5, +0, +5
	36	-5, +0, +5
delta BIOLOX V40	28	-4, -2.7, +0, +4
	32	-4, +0, +4
	36	-5, -2.5, +0, +2.5, +5, +7.5
delta Biolox C-Taper (when used with C-Taper Sleeve - catalog #17-0000E)	28	-2.5, +0, +2.5, +5
	32	-2.5, +0, +2.5, +5
	36	-5, -2.5, +0, +2.5, +5, +7.5
delta Biolox Universal Taper (when used with Universal Taper Sleeve - catalog #6519-T-XXX)	28	-2.5, +0, +4
	32	-2.5, +0, +4
	36	-2.5, +0, +4
	40	-2.5, +0, +4
	44	-2.5, +0, +4

Optional Step

When selecting a BIOLOX delta Universal Taper Ceramic Femoral Head (6519-1-0xx) for implantation, use of a Universal Adaptor Sleeve is necessary.

Catalog No.	Offset (mm)	Taper
6519-T-025	**-2.5**	**V40**
6519-T-100	**+0**	**V40**
6519-T-204	**+4**	**V40**

After completing the trialing process, intra-operatively assemble the adaptor sleeve to the femoral stem manually. The Universal Adaptor Sleeve must be fully seated on the stem taper before the head is assembled.

Note

In no instance should any attempt be made to pre-assemble the adaptor sleeve inside the BIOLOX delta Universal Ceramic Head.

Intra-operatively assemble the BIOLOX delta Universal Taper Ceramic Head onto the sleeved femoral stem and set with two moderate strikes using the Head Impactor. Care must be taken to avoid excessive impact forces when assembling the Ceramic Head to the sleeved femoral component.

165mm Length Straight Femoral Stem

Implant Catalog No.	Description
6260-6-111	No. 1 / 11mm
6260-6-212	No. 2 / 12mm
6260-6-113	No. 1 / 13mm
6260-6-313	No. 3 / 13mm
6260-6-214	No. 2 / 14mm
6260-6-414	No. 4 / 14mm
6260-6-315	No. 3 / 15mm
6260-6-515	No. 5 / 15mm
6260-6-416	No. 4 / 16mm
6260-6-616	No. 6 / 16mm
6260-6-517	No. 5 / 17mm
6260-6-717	No. 7 / 17mm
6260-6-618	No. 6 / 18mm
6260-6-818	No. 8 / 18mm
6260-6-719	No. 7 / 19mm
6260-6-820	No. 8 / 20mm
6260-6-921	No. 9 / 21mm

203mm Length Straight Femoral Stem

Implant Catalog No.	Description
6260-8-111	No. 1 / 11mm
6260-8-212	No.2 / 12mm
6260-8-113	No. 1 / 13mm
6260-8-313	No. 3 / 13mm
6260-8-214	No. 2 / 14mm
6260-8-414	No. 4 / 14mm
6260-8-315	No. 3 / 15mm
6260-8-515	No. 5 / 15mm
6260-8-416	No. 4 / 16mm
6260-8-616	No. 6 / 16mm
6260-8-517	No. 5 / 17mm
6260-8-717	No. 7 / 17mm
6260-8-618	No. 6 / 18mm
6260-8-818	No. 8 / 18mm
6260-8-719	No. 7 / 19mm
6260-8-820	No. 8 / 20mm
6260-8-921	No. 9 / 21mm

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