



*Profemur*<sup>®</sup>  
**GLADIATOR**<sup>®</sup>

Classic Stems - Surgical Technique

# INDICATIONS AND WARNINGS PROFEMUR® GLADIATOR® HIP STEMS

## INDICATIONS

PROFEMUR® GLADIATOR® Plasma Classic stems (PRGLCLE[1-9]; PRGLCE10; PRGLCLS[1-9]; PRGLCS10), PROFEMUR® GLADIATOR® HA Classic w/collar (PGHCCLS[1-9], PGHCCS10, PGHCCLE[1-9] and PGHCCE10) and w/o collar (PRGLHAS[1-10] and PRGLHAE[1-10]) stems are intended for uncemented arthroplasty. The hydroxyapatite and titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.

PROFEMUR® GLADIATOR® Cemented Classic stems (PRGCCMS[4-8]; PRGCMS[10-12]; PRGCCME[4-8]; PRGCME[10-12]) are intended for cemented arthroplasty.

PROFEMUR® GLADIATOR® Distal Centralizers (PRGLDC[04-12]) are intended for optional use as part of a cemented total hip arthroplasty with the PROFEMUR® GLADIATOR® hip stem and are packaged separately.

### Intended Use

MicroPort total hip devices are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

### Indications for Use Global (excluding EU, UK, NZ, and Australia)

- 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2) inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3) correction of functional deformity; and,
- 4) revision procedures where other treatments or devices have failed

### EU, UK, NZ, and Australia Only

#### Indications for Use – uncemented femoral stems

- 1) non-inflammatory degenerative joint disease such as osteoarthritis

#### Indications for Use – cemented femoral stems

- 1) non-inflammatory degenerative joint disease such as osteoarthritis
- 2) femoral neck fracture

## CONTRAINDICATIONS

Patients should be warned of these contraindications.

### Contraindications include:

- 1) overt infection;
- 2) distant foci of infections (which may cause hematogenous spread to the implant site);
- 3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- 4) skeletally immature patients (patient is less than 21 years of age at the time of surgery);
- 5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
- 6) neuropathic joints;
- 7) hepatitis or HIV infection;
- 8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

### Important

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on this or her personal medical training, experience, and patient condition.

Prior to use of the device, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and diverse effects. Instructions for Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique, and the Instructions for Use package insert is available on the website listed.

Package inserts are also available at [ortho.microport.com/ifus](http://ortho.microport.com/ifus)

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# Foreword

The Profemur® Gladiator® hip device is suitable for a range of indications from the low demand hip fracture population to the higher demand arthroplasty patient. The Profemur® Gladiator® cementless stems provide flexible primary THA options, featuring a tapered-wedge geometry designed for mediolateral stability, horizontal and vertical macro-features designed to distribute loading forces and promote rotational stability, proximal plasma coating, and a reduced lateral shoulder to help conserve bone and ease insertion.

The device has also been designed to accommodate surgeons' varied principles and techniques in the treatment of functional deformity, with the addition of a cemented stem. The Profemur® Gladiator® Cemented stem has geometry identical to the cementless versions, but with a smooth surface as opposed to the macro-features. Not all cases of functional trauma and genetic deformity are alike, nor should they be treated as such.

Profemur® Gladiator® stems provide choices for addressing:

- Variances in patient bone quality (whether to use a cemented or cementless stem)
- Concerns for use of cement in medically compromised patients
- Differences in surgeon philosophy on stem design and implant fixation

Surgeons and surgical staff will appreciate these design features made to improve your surgical experience and improve patient care options.

## This surgical technique was developed in collaboration with:

**Michael J. Anderson, MD**  
// Aurora Advanced  
Healthcare  
Milwaukee, WI

**Lowry Barnes, MD**  
// Arkansas Specialty  
Orthopaedics  
Little Rock, AR

**William M. Ricci, MD**  
// Washington University  
School of Medicine  
St. Louis, MO



# Profemur® Gladiator® HA-Coated Stems

## Ordering Information

Templates PRGLHXR15

Surgical Technique 025944

Instruments APHCL000 General Inst. Set  
PRGLKIT6 Gladiator® Set

Implants PGHAKITC HA Collared Stems  
PRGLKITH HA Collarless Stems

PRGLKITD HA Collarless Stems

CERAKITA Ceramic Heads



**Lateral Shoulder**  
Reduced material helps to conserve bone and ease insertion

**Collar**  
Provides rotational stability and protection against subsidence

**Sizes**  
Collared and collarless stems are available in sizes 1 - 10

**Common Instrumentation**  
Utilizes same set of broaches for all stem versions

**Macrofeatures**  
Provides additional rotational stability and maximizes compressive loading forces

**HA Coating**  
Enhances osteointegration and fixation

**Material**  
HA-Coated stems are made from forged Titanium Alloy (Ti6Al4V)

**Reduced Tip**  
To minimize point contact in the thigh for comfort



# Profemur® Gladiator® Cemented Stems

## Ordering Information

Templates	PRGLXR15	
Surgical Technique	025944	
Instruments	APHCL000	General Inst. Set
	PRGLKIT6	Gladiator® Set
Implants	PGCLKITC	Cemented Stems and Centralizers
	SUFIKITA	Metal Heads
	CERAKITA	Ceramic Heads

**Collar**  
Provides rotational stability and protection against subsidence

**Material**  
Cemented stem is made from forged Cobalt Chrome Alloy

**Centralizers**  
Available for each size of implant for a 1.5 mm distal circumferential cement mantle

*NOTE: Centralizers are provided in separate package*



**Driving Platform**  
Slotted driving platform for rotational control during stem insertion

**Lateral Shoulder**  
Reduced material helps to conserve bone and ease insertion

**Matte finish**

**Common Instrumentation**  
Utilizes same set of broaches for all stem versions, with 1.5mm/side cement mantle built-in to cemented stem sizes

**Sizes**  
Cemented stems are available in 5 sizes (4 - 6 - 8 - 10 - 12)

**Reduced Tip**  
To minimize point contact in the thigh for comfort



# Profemur® Gladiator® Plasma Stems

## Ordering Information

Templates	PRGLXR15	
Surgical Technique	025944	
Instruments	APHCL000	General Inst. Set
	PRGLKIT6	Gladiator® Set
Implants	PGCLKITP	Plasma Classic
	SUFIKITA	Metal Heads
	CERAKITA	Ceramic Heads



**Lateral Shoulder**  
Reduced material helps to conserve bone and ease insertion

**Plasma Spray**  
Provides additional 1mm press-fit (0.5mm/side) for initial stability and long-term on-growth

**Common Instrumentation**  
Utilizes same set of broaches for all stem versions

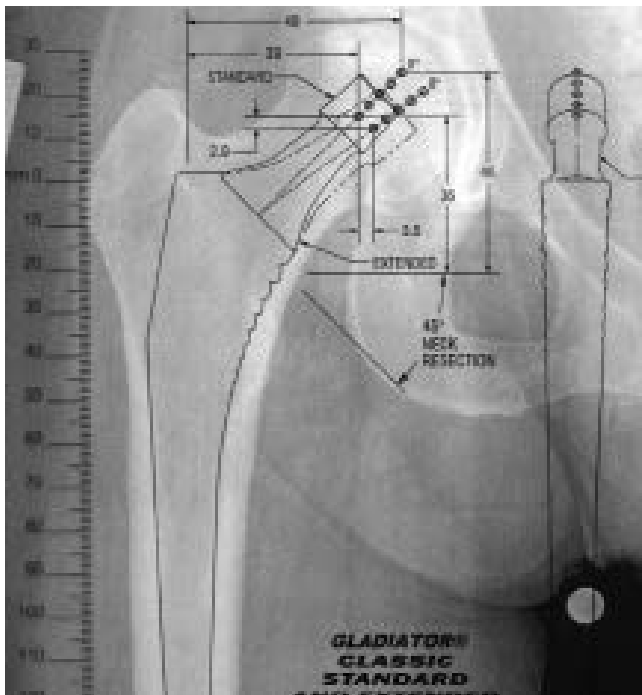
**Material**  
Plasma stems are made from forged Titanium Alloy (Ti6Al4V)

**Macrofeatures**  
Provide additional rotational stability and maximize compressive loading forces

**Sizes**  
Plasma stems are available in sizes 1 - 10

**Reduced Tip**  
To minimize point contact in the thigh for comfort

# Preoperative planning



The approximate femoral size and length of the femoral neck cut can be estimated from the templates. Neck angle and head length which most closely correspond to the patient's femoral head center can be estimated as well. The ideal head will align atop the previously determined center of rotation for the femoral head. In patients with significant deformity of the femoral head, templating can be performed on the opposite hip if necessary.

For soft bone, the implant may seat further than the template indicates. An implant larger than the templated size may be required. For strong, healthy bone, an implant smaller than the templated size may be required. The lateral X-ray illustrates the front to back fill of the implant and the position of the implant relative to the femoral anterior bow. If the anterior bow is high, the implant size may be reduced to minimize the risk of fracture.

**CAUTION:** Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively.

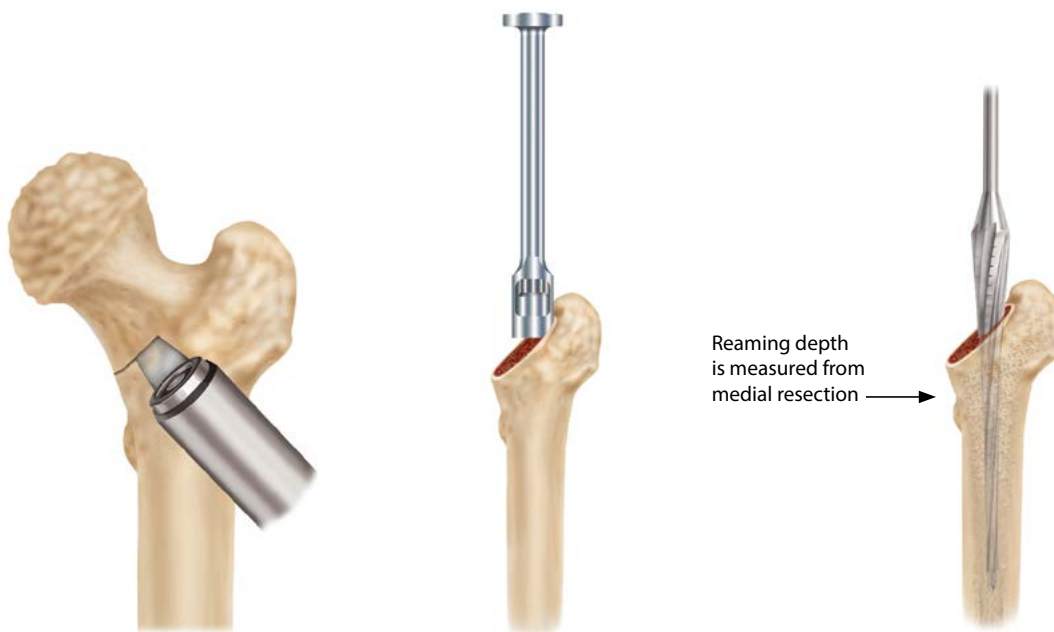
Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip. To determine limb length discrepancy—draw a line across the bottom of the ischium on the A/P view. The distance from this horizontal reference line to each lesser trochanter should then be measured. The difference between each measured side is the leg length discrepancy. If there is any asymmetry of the pelvis or if landmarks are not clear, other means to determine discrepancy should be used.

Determine the femoral head center. Once the center of rotation for the acetabular component has been determined, the center of rotation for the femoral head should be determined. Superimpose the femoral stem templates sequentially on the A/P X-ray with the templates positioned neutrally along the longitudinal axis of the femur. Estimate the metaphyseal and diaphyseal fit and anticipated level of implant insertion using the templates.





# Surgical Technique



## Femoral Neck Osteotomy

Using the greater trochanter or lesser trochanter as a reference, resect the neck at a 45° angle to the longitudinal axis of the femur.

## Femoral Canal Preparation

Using the box chisel (PPR67704-included in APHCL000), open the femoral canal. The box chisel should be lateralized to ensure a neutral orientation of the implant.

## Starter Reamer

Enter the femoral canal with the Profemur® Gladiator® starter reamer (PRGLREAM). Machined grooves along the surface of the starter reamer indicate the medial lengths of the corresponding stem sizes and reflect the proper depth at which to ream. Attach the T-handle onto the starter reamer, and ream to the appropriate depth according to preoperative templating. Manual reaming of the femur using the quick disconnect T-handle (K0001016) is recommended to avoid over-reaming the canal, to maintain alignment control and to minimize the amount of heat generated. If powered reaming is preferred, the T-handle can be removed and the starter reamer inserted into any surgical drill.



Box Chisel  
PPR67704



Profemur® Gladiator® Starter Reamer  
PRGLREAM



Quick Disconnect T-Handle  
K0001016



### Starter Broach

Prepare the femoral canal with the initial Profemur® Gladiator® Starter Broach (PRGLSTBR). Stay centered between the anterior and posterior cortices. Insert the broach using impactions until it rests 1-2mm below the level of the neck resection.

### Femoral Broaching

Attach the Broach Handle (PPW38078) to the size 1 Profemur® Gladiator® broach (PRGLBR01). Using a mallet with short, controlled strokes, begin broaching.

Sequentially increase the broach sizes while broaching (PRGLBR01 - PRGLBR12). Throughout broaching, continue to apply lateral pressure to ensure neutral alignment of the implant.

Continue broaching until an optimal fit is found. This will be denoted by a change in tone or resistance as the rounded corners of the broach contact the cortical bone of the femur. To verify a secure fit, attempt to rotate the broach relative to the femur. With proper cortical contact, the broach should not twist or move relative to the femur. At this point, leave the broach fully seated in the canal and detach the broach handle to allow for trial reduction.

### Cemented Stem/Rasp Combination

Stem Label	Rasp used to implant
4	4
6	6
8	8
10	10
12	12

NOTE: Broach sizes 11 and 12 are to be used for cemented application only.

1. Cementless stems have been dimensioned across the M/L width with a 1mm increment between sizes, except between size 1 and 2.
2. Cemented stems are dimensioned as the corresponding cementless sizes and implanted with bigger rasps. However, to facilitate the implantation, the stems are labeled as the corresponding rasps used during surgery. This will guarantee a uniform 1.5mm cement mantle thickness around the entire stem length.

The broach handle shows a scale to assist in determining the seating of the broach (and therefore the corresponding implant) in relation to the tip of the greater trochanter. The outcome can be compared with the preferred implant size/position determined during pre-planning.



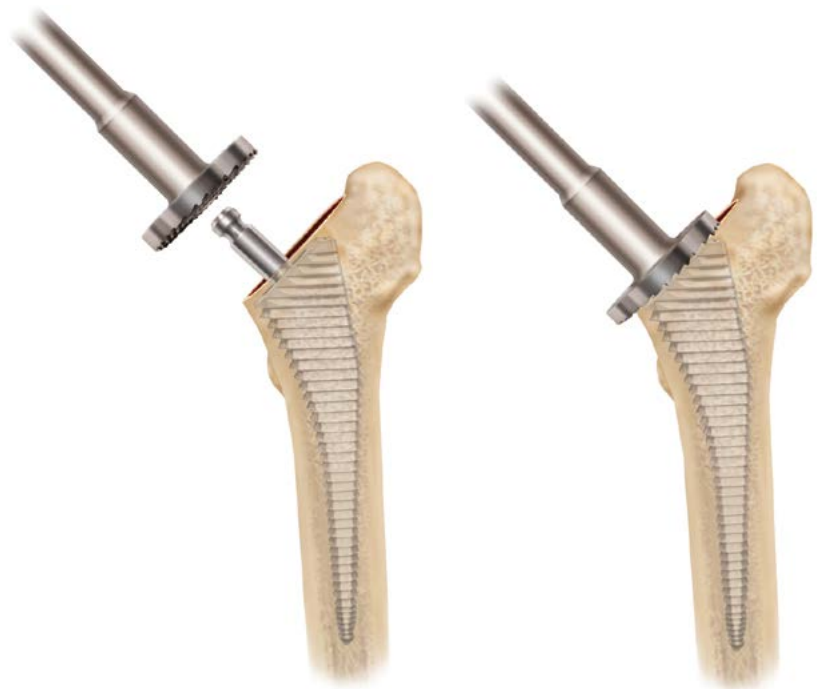
Profemur® Gladiator® Starter Broach  
PRGLSTBR



Broach Handle  
PPW38078



Profemur® Gladiator® Broach  
PRGLBR01-12



Potential differences between broaches and templated sizes:

- The quality of bone plays an integral role in sizing. For soft bone, the broach may seat further than the template indicates. An implant larger than the templated size may be required. Patients with strong, healthy bone might require an implant smaller than the templated size.
- If a broach smaller than the size templated becomes tight, hard bone at the lateral femoral neck may be pushing the broach into varus. Use the lateral edge of the broach to restore a neutral position. Additional broaching may be necessary.
- If a broach is going in straight and becomes tight with sizes smaller than those templated, a repetitive in/out broach motion may clear excess medial and lateral bone. If still tight, the stem should be appropriately downsized until metaphyseal bone is engaged.

## Calcar Planing

For collared stems, finish preparing the femur with the calcar planer (4700CP0000 and PRGLPOST). The calcar planer provides a reliable, effective, and accurate cutting instrument for the removal of hard calcar bone. Insert the Profemur® Gladiator® centralizer post (PRGLPOST) into the broach pocket. Attach the calcar planer (4700CP0000) to the drill and load onto the guide.

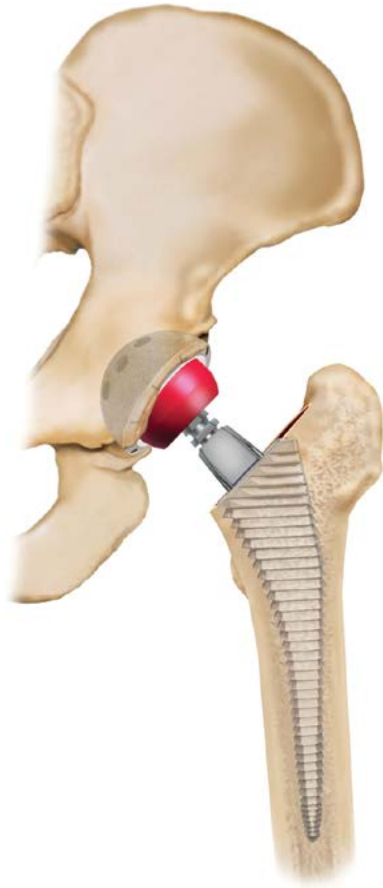
When planing, be sure to have the planer rotating prior to contacting the bone. With the built-in stop mechanism, the planer will stop at the appropriate level.



Centralizer Post  
PRGLPOST



PERFECTA® Calcar Planer  
4700CP0000



### Trial Reduction

Select the appropriate Profemur® metal trial neck (PRCLSTMN Straight and PRCLEXMN Varus 8°) and trial head (not included in PRGLKIT6) and perform a trial reduction. Once a well-balanced hip has been created with a trial head and trial neck, remove the broach.

### Brief Summary of neck options

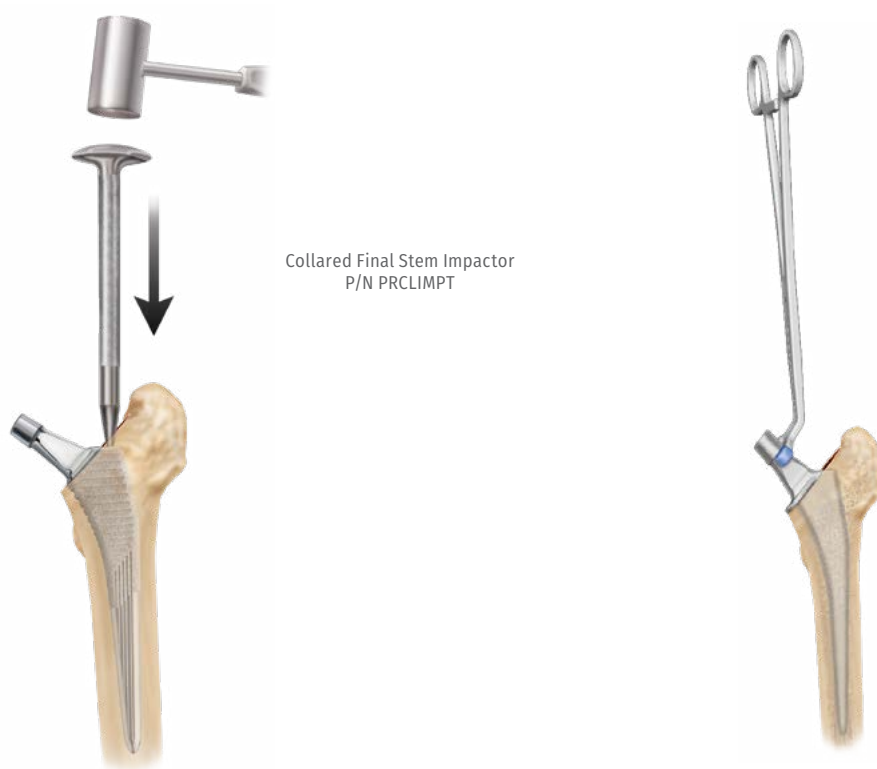
- Straight necks create a neutral neck axis (135°)
- Varus necks decrease the inclination angle to 127° (neutral position is 135°); the femoral head shifts medially and inferiorly; leg length is shortened; offset is increased.



Profemur® Gladiator®  
Classic Standard Metal Trial Neck  
PRCLSTMN



Profemur® Gladiator®  
Classic Extended Metal Trial Neck  
PRCLEXMN



Collared Final Stem Impactor  
P/N PRCLIMPT

### Stem insertion - cementless

Insert the femoral implant into the canal and seat it as far as possible by hand while maintaining proper version.

Use the Profemur(R) Classic Stem Impactor (P/N PRCLIMPT) to engage the oval slot on the lateral shoulder for rotational control (use only with collar stems).

Place the tip of the Final Stem Impactor (P/N PPF60200) into the dimple on the proximal face and, with a mallet, fully seat the implant using short, controlled strokes. Typically, the implant is seated with the base of the polished neck or the underside of the collar at the resection cut.

The Profemur® Gladiator® Plasma implants may sit 1-2mm proud than templated due to the additional 0.5mm thickness per side of the plasma. The difference can be addressed during the final trial reduction by selecting the proper head and neck combination.

### Stem insertion - cemented

The femoral bone bed is cleaned and bone cement is prepared and introduced into the femoral canal according to standard recommendations. Each stem has an appropriately-sized distal centralizer.

Place the centralizer onto the distal stem and affix by applying light pressure. The molded arrows on the edges of the centralizers are to point proximally and be oriented on the medial and lateral sides of the stem.

Insert the stem into the femoral canal by hand, and continue pushing the implant distally using the Modular Neck Inserter (P/N 20070050) until its final depth is reached. Stabilize the implant during cement curing and remove all excess cement. Typically, the implant is seated with the underside of the collar at the resection cut.

### Final trial reduction

Perform a final reduction using the trial heads to reconfirm stability, range of motion and leg length.



Final Stem Impactor  
P/N PPF60200



Collared Final Stem Impactor  
P/N PRCLIMPT



Modular Neck Inset  
P/N 20070050



## Head assembly

Ensure the stem taper is clean and dry prior to assembly, and then affix the femoral head to the neck. Using the head impactor instrument, strike the impactor with three very firm blows with a mallet to securely fix the head to the stem.

**NOTE:** Place a femoral head impactor with a plastic impaction tip (such as P/N 4400FI0000 or PPR67702) on ceramic head, and align the impactor with the femoral neck axis of the stem implant. With a moderate tap of the hammer in an axial direction, firmly impact the ceramic head until it is fully seated.

Position the leg such that the knee is supported by an assistant on the opposite side of the table. By resting the patient's knee against the mid-section of the assistant, this will provide counter-force against the mallet blows to ensure the impaction load transfer to the neck junction.

# Implant removal

## Classic stem removal

Should the removal of a Profemur® Gladiator® Classic stem become necessary, the Universal Stem Extractor (P/N 4700SE05) and the corresponding Slap Hammer (P/N 4700SH0000) can be utilized. Thread the stem extractor onto the threaded end of the slap hammer. With the femoral head removed, position the stem extractor across the flats on the sides of the femoral neck, and remove the stem using repetitive upward blows delivered by the slap hammer.

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

NOTE: Classic stem extraction instruments must be ordered separately.



Slap Hammer  
P/N 4700SH0000



Universal Stem Extractor  
P/N 4700SE05



# Technique Overview



1. Femoral Neck Osteotomy



2. Box Osteotome



3. Starter Reamer



4. Starter Broach



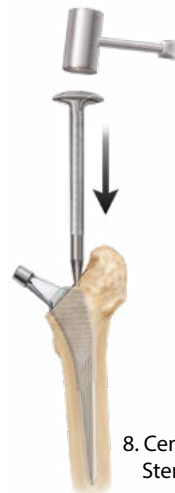
5. Femoral Broaching



6. Calcar Planing



7. Trial Reduction



8. Cementless Stem Insertion



9. Cemented Stem Insertion

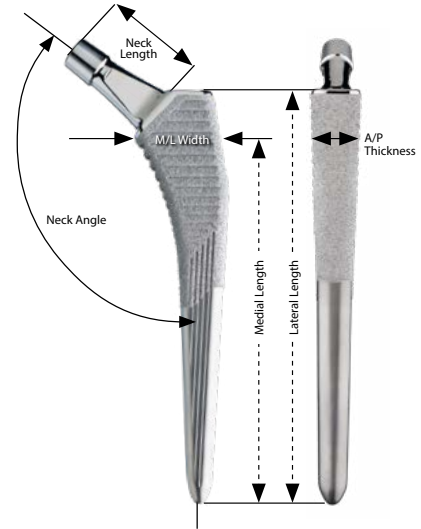


10. Femoral Head Assembly

# Implant Specifications

## Profemur® Gladiator® Stems General Specifications

- » Titanium material (cementless stems)
- » CoCr material (cemented stems)
- » Medial Width: 27 – 36mm
- » A/P Thickness: 12 – 19mm
- » Classic Straight neck angle is 135°
- » Classic Varus 8° neck angle is 127°



### Dimensional Chart

Profemur® Gladiator® Hip Stems (Measurements in millimeters)

	Classic Neck		Stem Measurements				
	Size	Leg Length	Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
	<b>Straight (135°)</b>						
Plasma/HA	1	31	37	107	27	12	125
	2	31	38	117	28	12	135
	3	32	39	122	29	13	140
	4	32	40	127	30	14	145
	5	32	40	132	31	15	150
	6	32	41	137	32	16	155
	7	33	42	142	33	17	160
	8	33	43	147	34	18	165
	9	33	44	152	35	18	170
	10	34	44	157	36	19	175
Cemented	4	32	40	107	27	12	125
	6	32	41	122	29	13	140
	8	33	43	132	31	15	150
	10	34	44	142	33	17	160
	12	35	45	152	35	18	170
	<b>Varus 8° (127°)</b>						
Plasma/HA	1	30	43	107	27	12	125
	2	30	43	117	28	12	135
	3	31	44	122	29	13	140
	4	31	45	127	30	14	145
	5	31	45	132	31	15	150
	6	32	46	137	32	16	155
	7	32	47	142	33	17	160
	8	32	48	147	34	18	165
	9	33	49	152	35	18	170
	10	33	50	157	36	19	175
Cemented	4	31	45	107	27	12	125
	6	32	46	122	29	13	140
	8	32	48	132	31	15	150
	10	33	50	142	33	17	160
	12	33	52	152	35	18	170

Offset & Leg Length are based on +0 head. Measurements are stem's substrate.  
Information provided for planning purposes.

### Head Adjustment Chart (Measurements in millimeters)

Head Size	Neck Length Adjustment	OFFSET / LEG LENGTH ADJUSTMENT	
		Straight	Varus 8°
Short	-3.5	-2.5 / -2.5	-2.8 / -2.1
Medium	+0	+0.0 / +0.0	+0.0 / +0.0
Long	+3.5	+2.5 / +2.5	+2.8 / +2.1
X Long	+7	+4.9 / +4.9	+5.6 / +4.2
XX Long	+10.5	+7.4 / +7.4	+8.4 / +6.3





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