Profemur® Gladiator®

Total Hip System: Classic and Modular Stems

SURGICAL TECHNIQUE

MicroPort Orthopedics

Full Function, Faster®

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MicroPort Orthopedics recognizes that 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 his or her personal medical training, experience and patient condition. Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse 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 inserts are available on the website listed.

Please contact your local MicroPort Orthopedics representative/ distributor for product availability

Preface

Design Rationale

Dear Orthopaedic Colleagues,

Over the last decades, Total Hip Arthroplasty has become a standard procedure. In order to obtain an optimal result, a perfect reconstruction and balance of the hip are essential. Simultaneous correction of leg length, offset, rotation, varus or valgus deformity seems to be impossible with one single hip system. After correct repositioning of the center of rotation, modular necks are an essential tool for perfect hip reconstruction.

Moreover, because of the diversity in proximal femoral geometry, one single stem design cannot cover all cases. The Profemur® Gladiator® Total Hip System was developed to offer a solution to these individual differences in the anatomy of the femoral canal. In order to deal with this variety in femoral canal index, the Profemur® Gladiator® stems are available in four options: cemented, plasma sprayed, hydroxyapatite collared and hydroxyapatite collarless.

This choice of femoral stem options with the Profemur® Gladiator® Total Hip System combined with the Microport neck modularity is offering the surgeon a highly valuable tool to achieve optimal hip reconstruction even in challenging cases.

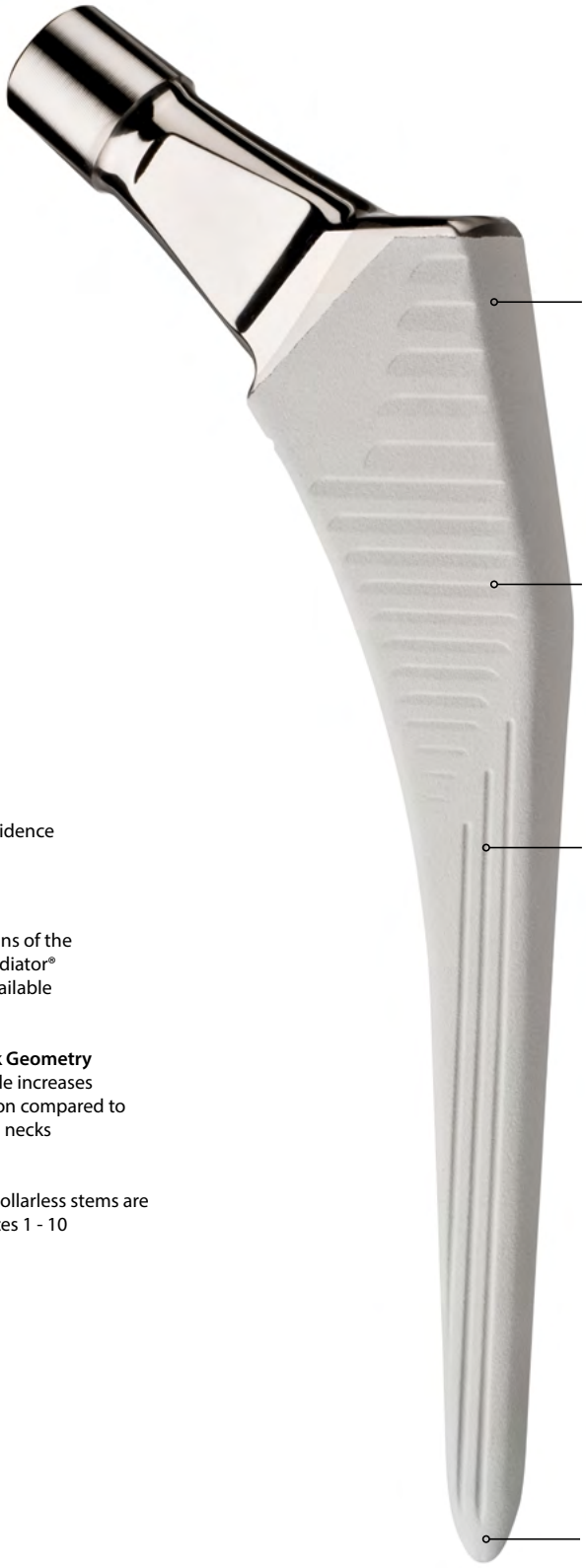
Sincerely,

The Surgeon Design Team

(Dr. Anderson, USA; Dr. Barnes, USA; Dr. Goossens, Belgium; Prof. Molé, France; Dr. Ricci, USA)

Profemur® Gladiator® HA-Coated Stems

Ordering Information		
Templates	PRGHXR15 (Modular) PRGLHXR15 (Classic)	
Surgical Technique	010484D	
Instruments	APH00000	General Inst. Set
	PRGLKIT4	Gladiator® Set
Implants	PRGLKITC	HA Collared Stems
	PRGLKITH	HA Collarless Classic Stems
	PRGLKITD	HA Collarless Stems
	COCRKITA	Modular Necks
	SUFIKITA	Metal Heads
	CERAKITA	Ceramic Heads



Lateral Shoulder
Reduced material helps to conserve bone and ease insertion

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)

Common Instrumentation
Utilizes same set of broaches for all stem versions

Reduced Tip
To minimize point contact in the thigh for comfort

Collar
Provides rotational stability and protection against subsidence

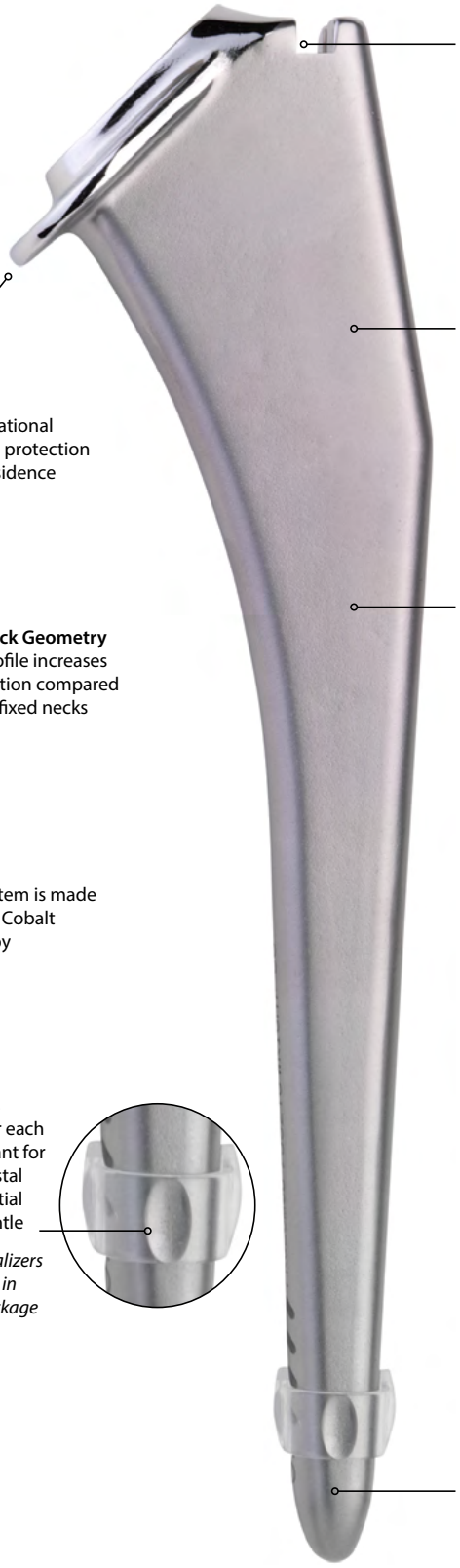
Modular options of the Profemur® Gladiator® HA are also available

Modular Neck Geometry
Reduced profile increases range of motion compared to standard fixed necks

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

Profemur® Gladiator® Cemented Stems

Ordering Information		
Templates	PRGCXR15	
Surgical Technique	010484D	
Instruments	APH00000	General Inst. Set
	PRGLKIT4	Gladiator® Set
Implants	PRGLKITA	Cemented Stems and Centralizers
	COCRKITA	Modular Necks
	SUFIKITA	Metal Heads
	CERAKITA	Ceramic Heads



Driving Platform
Slotted driving platform for rotational control during stem insertion

Lateral Shoulder
Reduced material helps to conserve bone and ease insertion

Collar
Provides rotational stability and protection against subsidence

Matte finish

Modular Neck Geometry
Reduced profile increases range of motion compared to standard fixed necks

Material
Cemented stem is made from forged Cobalt Chrome Alloy

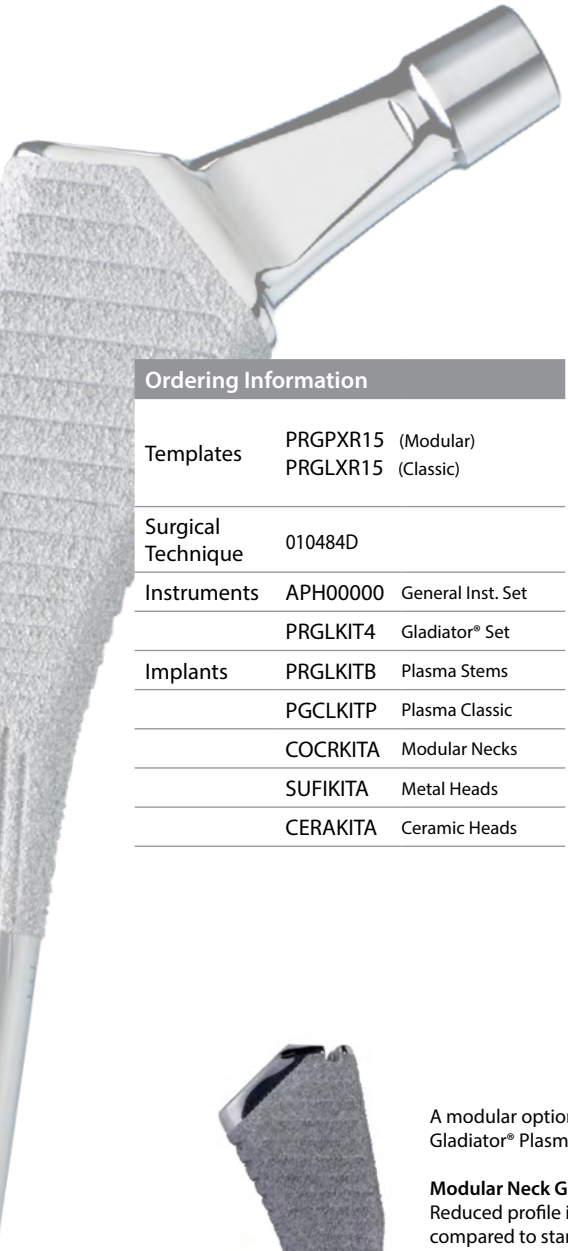
Common Instrumentation
Utilizes same set of broaches for all stem versions, with 1.5mm/side cement mantle built-in to cemented stem sizes

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

NOTE: Centralizers are provided in separate package

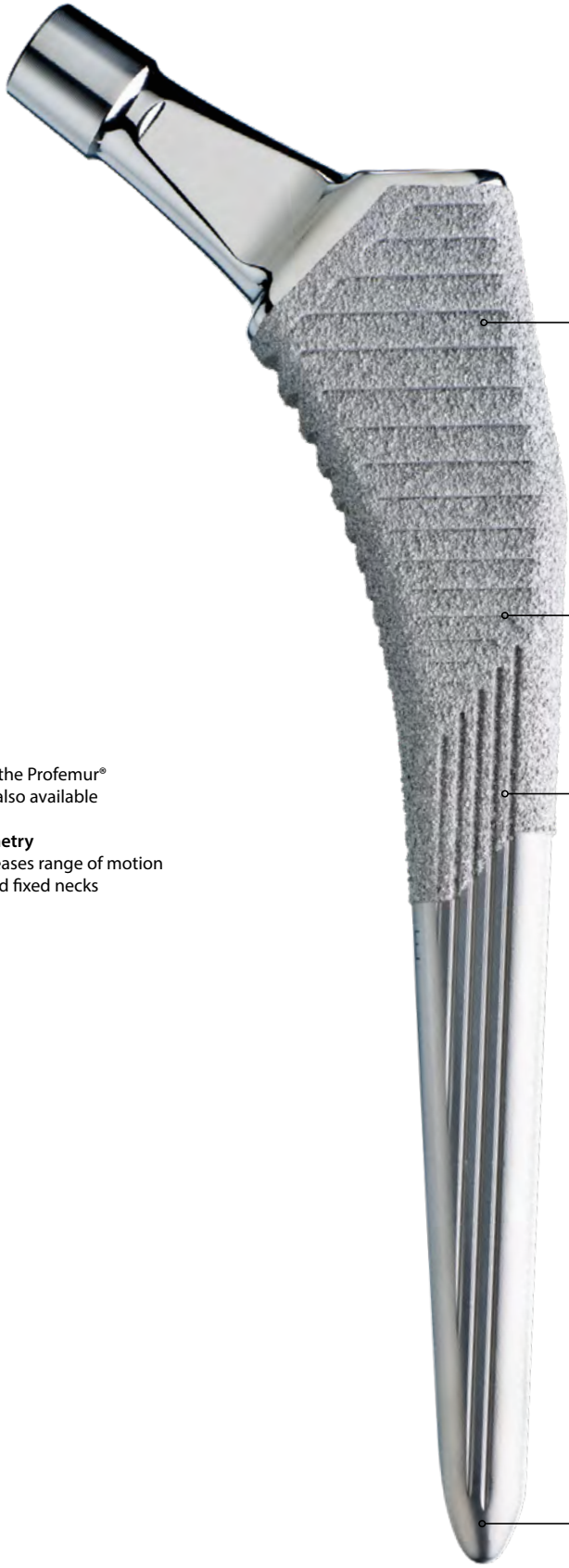
Sizes
Cemented stems are available in 5 sizes (4 - 6 - 8 - 10 - 12)

Reduced Tip
To minimize point contact in the thigh for comfort



Profemur® Gladiator® Plasma Stems

Ordering Information		
Templates	PRGPXR15 (Modular) PRGLXR15 (Classic)	
Surgical Technique	010484D	
Instruments	APH00000	General Inst. Set
	PRGLKIT4	Gladiator® Set
Implants	PRGLKITB	Plasma Stems
	PGCLKITP	Plasma Classic
	COCRKITA	Modular Necks
	SUFIKITA	Metal Heads
	CERAKITA	Ceramic Heads



Lateral Shoulder
Reduced material helps to conserve bone and ease insertion

Macrofeatures
Provide additional rotational stability and maximize compressive loading forces

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)

Sizes
Plasma stems are available in sizes 1 - 10

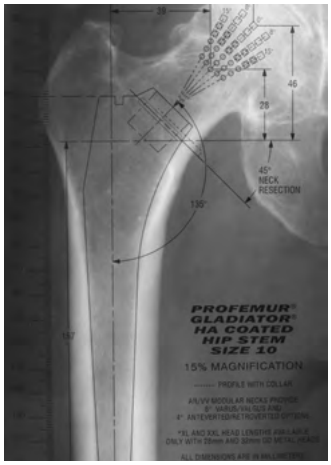
Reduced Tip
To minimize point contact in the thigh for comfort

A modular option of the Profemur® Gladiator® Plasma is also available

Modular Neck Geometry
Reduced profile increases range of motion compared to standard fixed necks

Chapter 1

Preoperative Planning



Preoperative Planning

NOTE: *Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip.*

Determine leg 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. The approximate femoral size and length of the femoral neck cut can be estimated from the templates. Neck angle, neck length, and head length which most closely correspond to the patient's femoral head center can be estimated as well. The circles/squares found along the femoral neck axis represent the expected centers of rotation for the femoral head. For the ideal neck/head combination, the circle/square 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.

Each circle represents the center of rotation for a modular short neck with the corresponding head option. Each square represents the center of rotation for a modular long neck with the corresponding head option. The circles/squares on the A/P template of the stem illustrate the impact of choosing an 8° varus/valgus neck relative to the neutral neck position.

NOTE: *AR/VV necks can also affect neck position by 6° varus/valgus.*

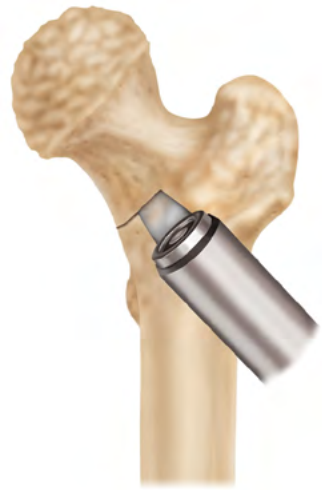
The lateral X-ray illustrates the front to back fill of the implant and the position of the implant relative to the femoral anterior bow. If the anterior bow is high, the implant size may be reduced to minimize the risk of fracture. The lateral templates use circles/squares to compare the impact of choosing a neutral neck and necks with 8° or 15° anteversion/retroversion.

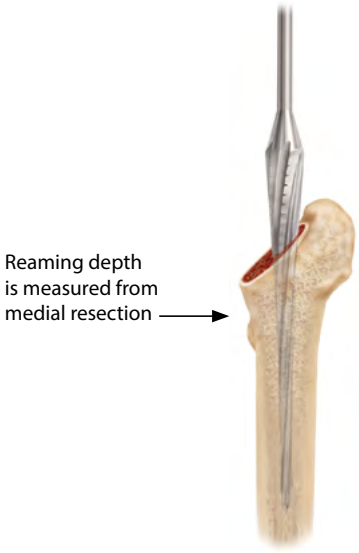
Both the A/P and lateral views are needed to illustrate the impact of choosing an AR/VV neck because the combination necks provide multi-dimensional positioning. Each AR/VV neck provides 4° anteversion/retroversion and 6° varus/valgus. The impact of each AR/VV option (1 or 2) depends upon which hip is being considered. Therefore, caution should be used to ensure that the appropriate combination is planned.

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

Chapter 2

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 APH00000), open the femoral canal. The box chisel should be lateralized to ensure a neutral orientation of the implant.

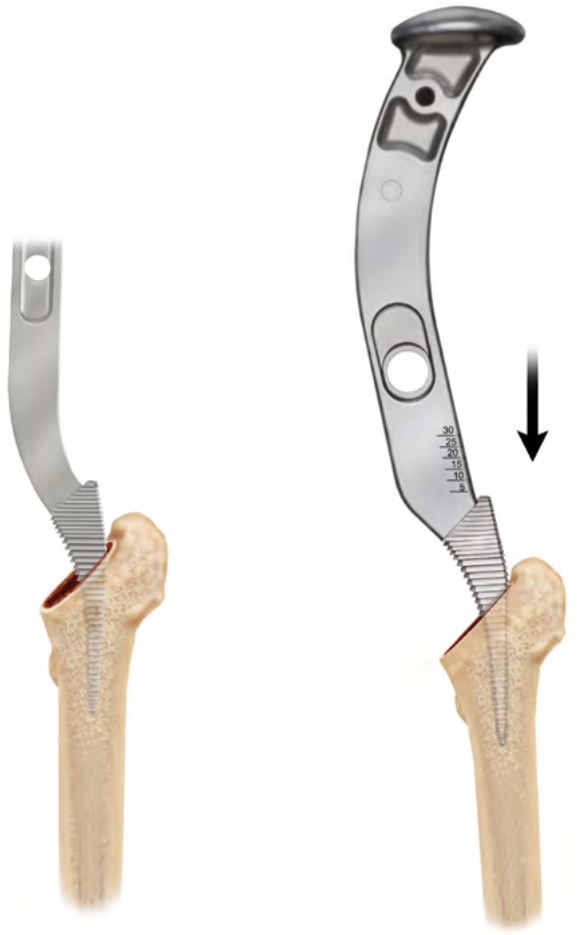
Starter Reamer

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



Cemented Stem/Rasp Combination

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

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.

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

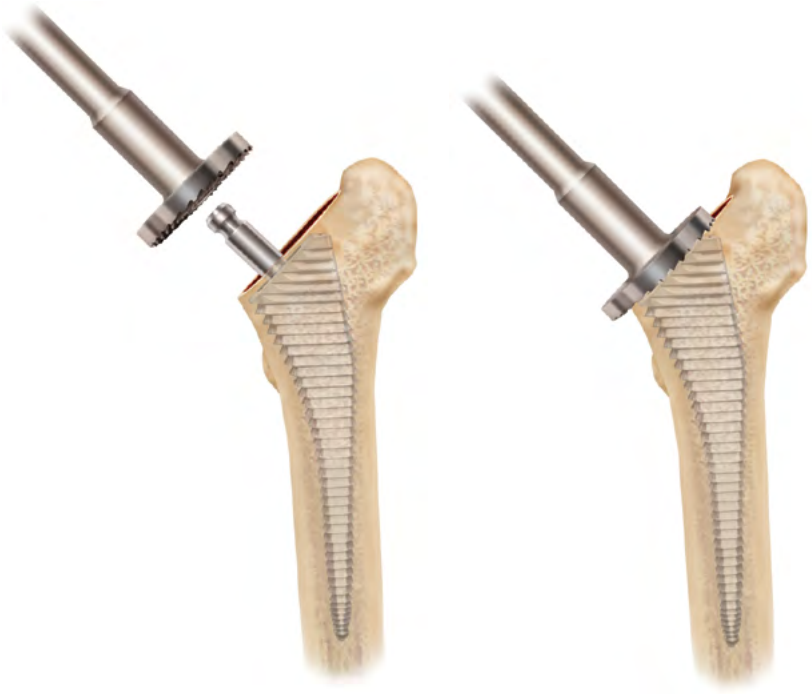
1. Cementless stems have been dimensioned across the M/L width with a 1mm increment between sizes, except between size 1 and 2.
2. Cemented stems are dimensioned as the corresponding cementless sizes and implanted with bigger rasps. However, to facilitate the implantation, the stems are labeled as the 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.

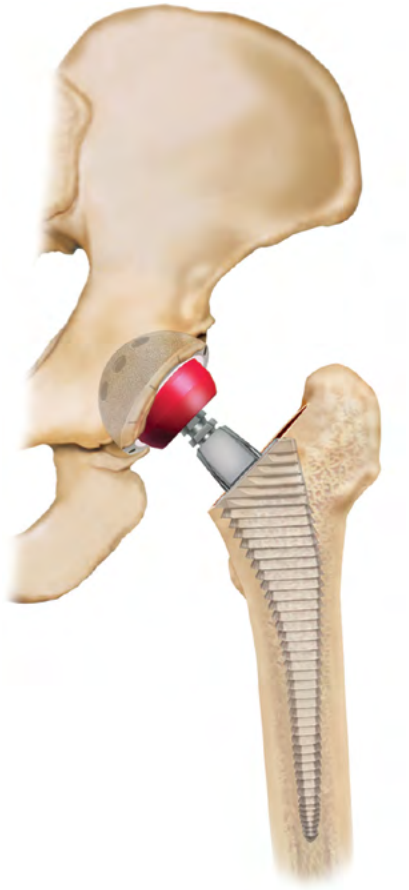
Calcar Planing

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 (APA12102 – APA12154) and trial head (not included in PRGLKIT4) and perform a trial reduction. Once a well-balanced hip has been created with a trial head and trial neck, remove the broach.

TIP: The choice of neck anteversion is based on intraoperative assessment of stability. The head/neck combination that allows maximal flexion/internal rotation and extension/external rotation without dislocation should be chosen.

NOTE: When implanting a Profemur® Gladiator® Classic, two dedicated trial necks have to be used (PRCLSTMN and PRCLEXMN). Those specific trial necks are not included in the PRGLKIT4 and have to be ordered separately.

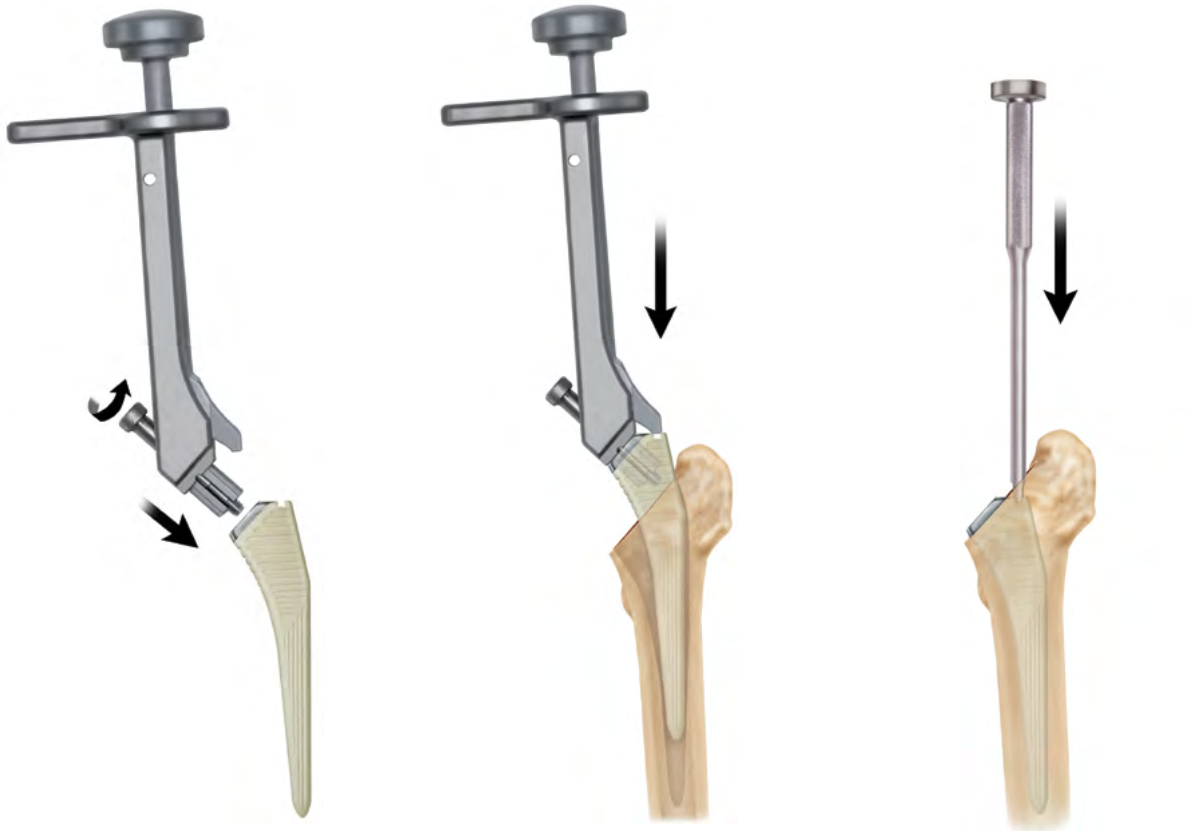
Brief Summary of Neck Options

- 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.
- Valgus necks increase the inclination angle to 143˚; the femoral head shifts laterally and superiorly; leg length is increased; offset is decreased.
- Anteverted necks shift the femoral head anteriorly relative to the stem by 8˚ or 15˚.
- Retroverted necks shift the femoral head posteriorly relative to the stem by 8˚ or 15˚. Retroverted necks prove useful in hips with excess femoral anteversion such as DDH.
- AR/VV necks combine anteversion/retroversion and varus/valgus necks to offer a broad range of multi-dimensional head positions. Each AR/VV neck provides 4˚ of A/R and 6˚ of V/V.

Profemur® Metal Trial Neck
APA12102-APA12154

Profemur® Gladiator®
Classic Standard Metal Trial Neck
PRCLSTMN

Profemur® Gladiator®
Classic Extended Metal Trial Neck
PRCLEXMN



Stem Insertion - Cementless

The stem is inserted with the special Stem Inserter (APA01114, included in APH00000). Use the hex screwdriver (PP275400, included in APH00000) to fix the implant in the impactor. The Profemur® screwdriver inserter (PRFS0460) can be used for final seating of the component.

NOTE: When using a collarless implant – the build up offset portion of the implant should not be completely impacted. The implant should be seated so that the base of the polished neck is at depth equivalent to the resection level.

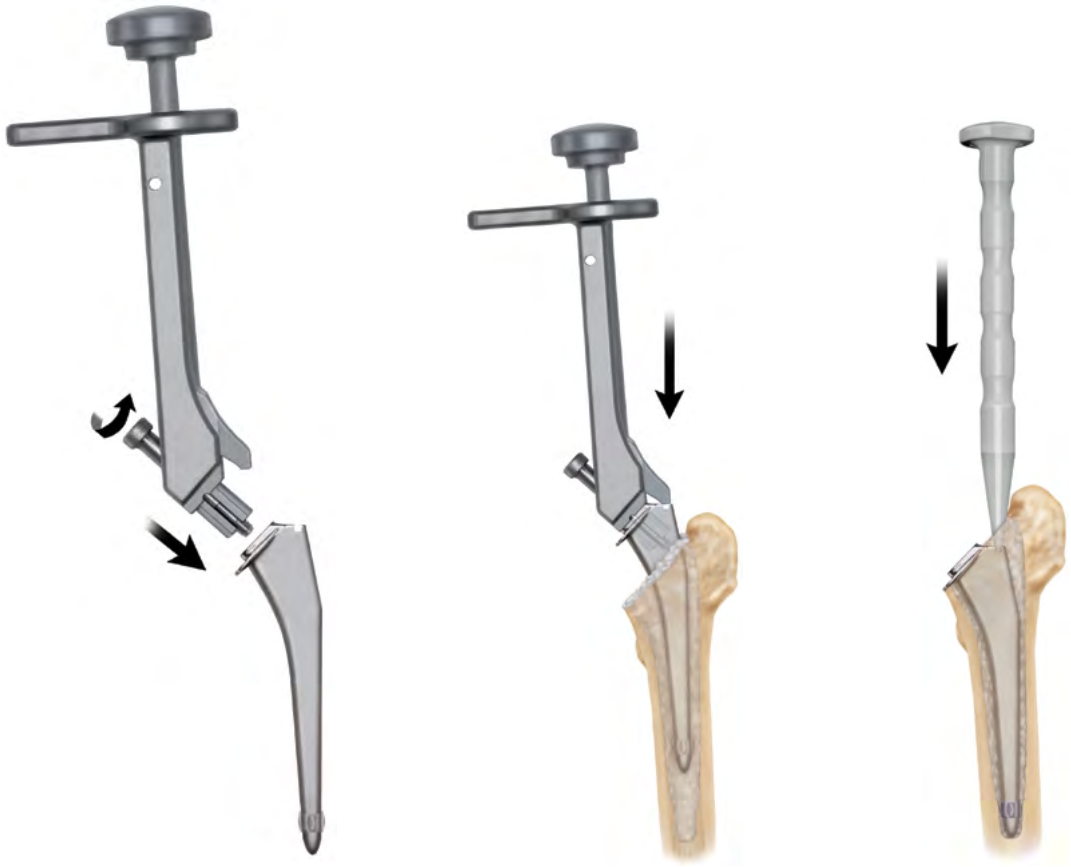
NOTE: For the Profemur® Gladiator® Plasma Spray version, the implant may sit 1 - 2mm more proud than templated due to the additional 0.5mm thickness per side of the plasma spray. The difference can be addressed during the final trial reduction by selecting the proper head and neck combination.

WARNING: APA09028 is a plastic pusher instrument intended to be used for cement application only to hold the stem in place while cement is curing. Do not use this instrument for impaction purposes or cementless application.

Stem Inserter
APA01114

Hex Screwdriver
PP275400

Profemur® Screwdriver Inserter
PRFS0460



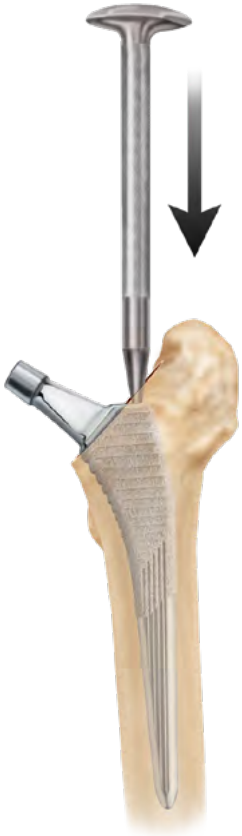
Stem Insertion - Cemented

The femoral bone bed is cleaned and bone cement is prepared and introduced into the femoral canal according to standard recommendations. Centralizers are provided packaged separately from the implants. Place the centralizer onto the distal stem and affix by applying light pressure.

NOTE: 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.

The stem is inserted using the special stem impactor (APA01114, included in APH00000). Use the hex screwdriver (PP275400, included in APH00000) to fix the implant in the impactor. The implant pusher (APA09028) can be used to stabilize the stem during the curing of the cement.

Implant Pusher
APA09028



Stem Insertion - Classic

Insert the femoral implant into the canal and seat it as far as possible by hand while maintaining proper version. Place the tip of the Final Stem Impactor (PPF60200, included in the APH00000) into the dimple on the lateral shoulder and, with a mallet, fully seat the implant using short, controlled strokes. Typically, the implant is seated with the base of the polished neck at the resection cut.

NOTE: For the Profemur® Gladiator® Plasma Classic, the implant may sit 1-2 mm more proud than templated due to the additional 0.5mm thickness per side of the plasma. To reconfirm the stability, range of motion and leg length of the definitive stem, a trial reduction can be performed using the appropriate trial head.

Final Stem Impactor
PPF60200

Final Trial Reduction

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

Select the appropriate Profemur® trial neck (APA11102-APA11154, included in APH00000) and trial head (APA02121-APA02154, included in APH00000) and perform a trial reduction. Once a well-balanced hip has been created with a trial head and trial neck you can introduce the final neck and head implant.

Step 1

Step 2

Step 3

Step 4

Implant Assembly

To properly assemble and impact a Profemur® Modular Neck the following procedure is recommended:

Step 1. Suction any fluid from the stem implant pocket. Ensure that both the stem and neck are clean and dry prior to assembly.

Step 2. Insert the oval end of the appropriate femoral neck implant into the femoral stem pocket.

Step 3. 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.

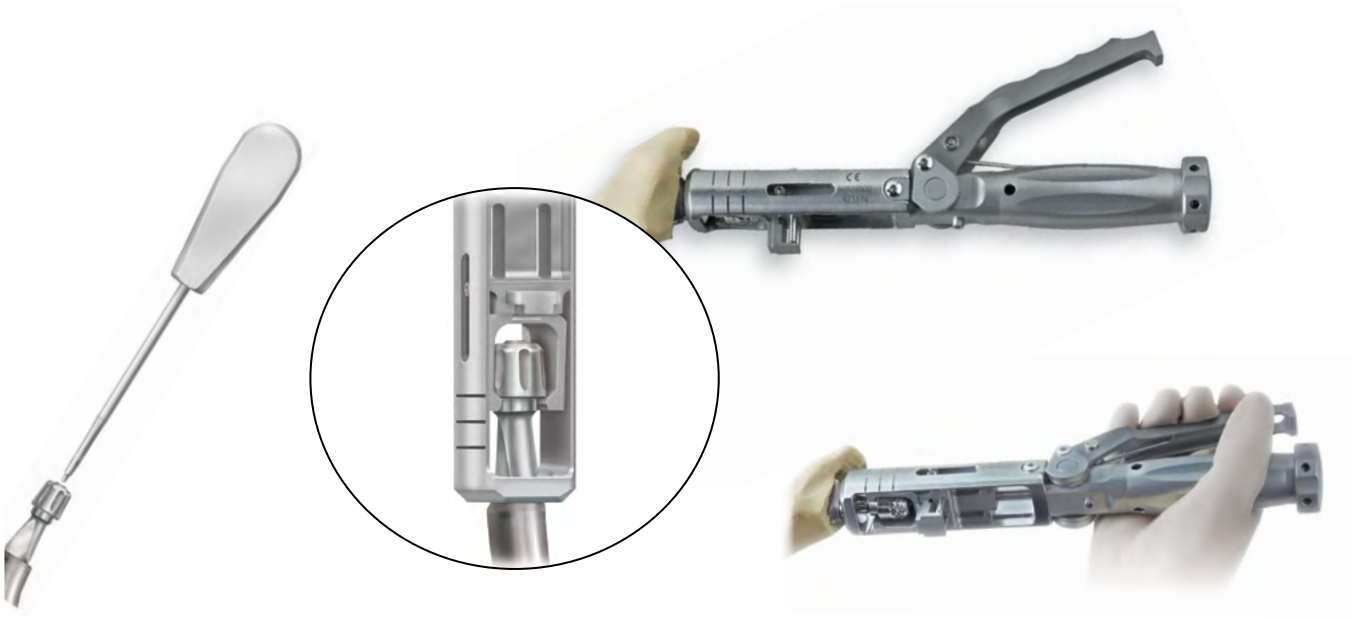
Step 4. Ensure the stem taper is clean and dry prior to assembly, and then affix the femoral head to the neck. Using the head impactor instrument, strike the impactor with three very firm blows with a mallet to securely fix the head to the neck and stem.

NOTE: *If using a ceramic head, securely fix the neck into the stem by impaction, then place the head on the neck by hand, push and turn the head 180° to securely lock it in place.*

NOTE: *If using the Profemur® Gladiator® Classic, affix the femoral head to the neck.*

Chapter 3

Implant Removal



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.

Femoral Head Removal

The femoral head is removed by placing a plastic tipped femoral head impactor under the femoral head and applying mallet blows upward until the femoral head is removed.

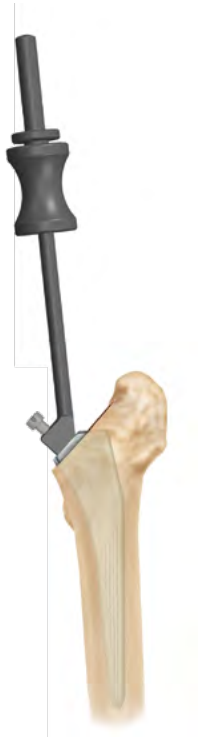
Femoral Neck Extraction

Screw the femoral neck adaptor (APA09501) onto the femoral neck in a clockwise motion. The neck extractor goes over the top of the femoral neck and the adapter is captured by the adjustable hook. By squeezing the handle an extraction force is applied to the neck as the neck extractor pushes against the shoulder of the prosthesis. The extractor will accommodate any style and size of neck in combination with any style and size of prosthesis.

Profemur® Modular Necks Extractor Kit

APH04600

Catalog#	Description
APA09500	Neck Extractor
APA09501	Adaptor 12/14 for Neck Extractor
APA09502	Wrench for Neck Extractor
PP275400	Hex Screwdriver
PRNETR01	Profemur® Neck Extractor Tray



Modular Stem Removal

The thread at the base of the modular neck pocket can now be accessed to remove the stem. Insert the Femoral Stem Extractor (PPR67688) into the modular neck pocket and tighten the threaded shaft by hand, followed by firmly seating the shaft via the use of the Hex Screwdriver (PP275400). Using the slide hammer portion, create extraction forces onto the underside of the femoral stem extractor strike plate to remove the stem. If bone on-growth exists, it may be necessary to use osteotomes in order to first disengage the stem/bone interface.

Classic Stem Removal

The PERFECTA® Universal Stem Extractor (4700SE05) and the corresponding Slap Hammer (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.

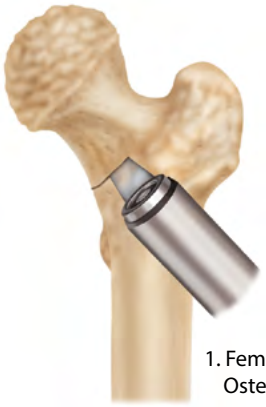
Femoral Stem Extractor
PPR67688

PERFECTA® Universal Stem Extractor
4700SE05

Slap Hammer
4700SH0000

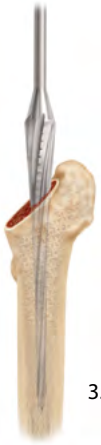
Chapter 4

Technique Overview

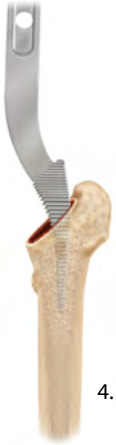


1. Femoral Neck Osteotomy

2. Box Osteotome

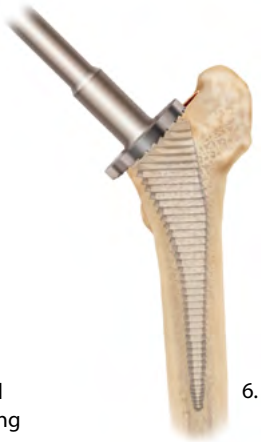


3. Starter Reamer

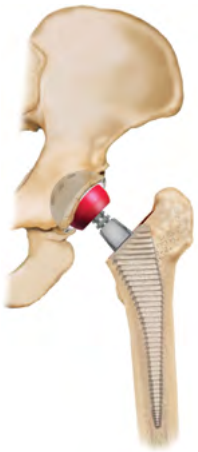


4. Starter Broach

5. Femoral Broaching



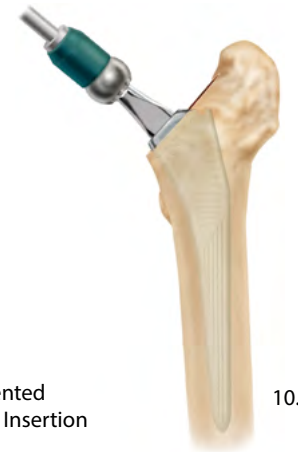
6. Calcar Planing



7. Trial Reduction

8. Cementless Stem Insertion

9. Cemented Stem Insertion

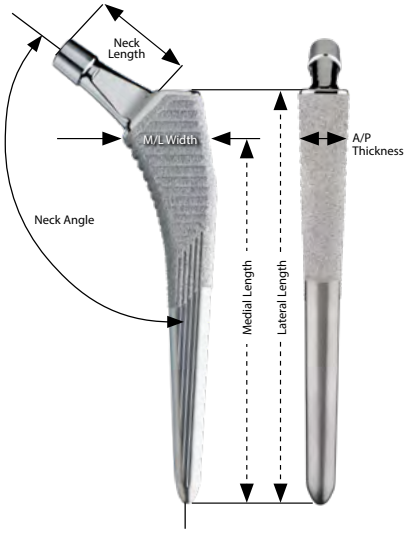


10. Modular Neck & Femoral Head Assembly

Chapter 5
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)

		Short Neck Modular		Medium Neck Classic		Long Neck Modular		Stem Measurements			
	Size	Neck Length	Offset	Neck Length	Offset	Neck Length	Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
	Straight (135°)										
Plasma/HA	1	28	35	32	37	39	42	107	27	12	125
	2	28	35	32	38	39	43	117	28	12	135
	3	28	36	33	39	39	43	122	29	13	140
	4	29	37	33	40	39	44	127	30	14	145
	5	29	38	33	40	40	45	132	31	15	150
	6	30	38	33	41	40	46	137	32	16	155
	7	30	39	34	42	41	47	142	33	17	160
	8	31	40	34	43	41	48	147	34	18	165
	9	31	41	35	44	42	48	152	35	18	170
	10	32	42	35	44	42	49	157	36	19	175
Cemented	4	29	35			39	43	107	27	12	125
	6	30	37			40	44	122	29	13	140
	8	31	39			41	46	132	31	15	150
	10	32	40			42	48	142	33	17	160
	12	32	41			42	49	152	35	18	170
	Varus 8° (127°)										
Plasma/HA	1	29	38	35	43	40	46	107	27	12	125
	2	29	38	35	43	40	47	117	28	12	135
	3	29	39	36	44	40	47	122	29	13	140
	4	30	40	36	45	40	48	127	30	14	145
	5	30	41	36	45	41	49	132	31	15	150
	6	31	41	37	46	41	50	137	32	16	155
	7	31	42	37	47	42	51	142	33	17	160
	8	32	43	38	48	42	52	147	34	18	165
	9	32	44	38	49	43	52	152	35	18	170
	10	33	45	39	50	43	53	157	36	19	175
Cemented	4	30	38			40	47	107	27	12	125
	6	31	40			41	48	122	29	13	140
	8	32	42			42	50	132	31	15	150
	10	33	43			43	52	142	33	17	160
	12	33	44			43	53	152	35	18	170

Offset & Neck Length are based on +0 head. Measurements are stem's substrate.
Long Varus Neck option is not available for Profemur®Modular Stems. Information provided for planning purposes.

Head Adjustment Chart
(Measurements in millimeters)

		OFFSET / LEG LENGTH ADJUSTMENT	
Head Size	**Neck 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

Chapter 6

Indications and Warnings

Indications and Warnings

Intended Use

MicroPort total hip systems 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:

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

Rough grit blast surfaces and the hydroxyapatite, titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.
(European Union Only) PROFEMUR® Gladiator cemented hip stem is not intended for use in revision arthroplasty.

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.

Additional contraindications for a metal-on-metal bearing include (Not available in U.S.):

1) Patients with known moderate to severe renal insufficiency;
2) Females of childbearing age are contraindicated due to the unknown effects of elevated levels of metal ions on the fetus.

Product-Specific Warnings and Precautions

Do not attempt to seat the implant beyond the envelope of femoral bone preparation. Forcing to seat the implant beyond the prepared femoral bone may increase the chance of bone fracture. In some cases, a portion of the proximal body with or without coating may be visible above the proximal resection level.

The smaller sized femoral implants are intended for patients with narrower intramedullary femoral canals. The geometry of these implants is reduced to accommodate the anatomy of the narrower intramedullary femoral canal, which also decreases the fatigue-strength and load-bearing characteristics of the implant.

Other Modular Components

Always follow the recommended surgical technique. Failure to adhere to the advised assembly instructions may have potential to increase risk of fretting corrosion, fretting fracture or disassociation of the product. Prior to assembly, surgical debris must be cleaned from the interior of the female seat to ensure proper locking. Ensure components are firmly seated to prevent disassociation. The femoral head, neck taper of the femoral component, modular neck tapers, body taper, female seat of the proximal body must be clean and dry before assembly. Impact according to the recommended surgical technique. Scratching of femoral heads, modular necks and proximal and distal stem tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Do not resterilize femoral prostheses with ceramic femoral heads seated on the stem, as sterilization may cause undetectable ceramic damage. Please refer to the section below named Hip Bearing System or specific warnings and precautions regarding ceramic femoral heads.

Stems and modular necks with the 12/14 SLT Taper should only be used in combination femoral heads with the 12/14 SLT Taper. Cobalt chrome femoral heads with the 12/14 SLT Taper are designed for use with cobalt-chrominum-molybdenum, titanium alloy and (ISO 5832-9) stainless steel femoral components with the 12/14 SLT Taper and to articulate with UHMWPE bearings only. The superfinished cobalt chrome femoral heads are designed to articulate with UHMWPE bearings.

Ceramic femoral heads should not be placed on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

CoCr Modular necks are not for use with the following devices:

• Alumina (Biolox® Forte) Ceramic Femoral Head size 28mm long

• Profemur® E Size 0 Hip Stem

Do not place ceramic components on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

The ceramic femoral head is placed on the stem taper by twisting lightly and using axial manual pressure until it sits firmly.

Place the plastic head impactor on the pole of the ceramic femoral head, and with a moderate tap of the hammer in an axial direction, firmly and definitively fix it on the stem taper. The surface structure of the metal taper becomes distorted plastically by the tapping of the impactor, causing an optimal distribution of pressure and a torsion-resistant fixation.

On rare occasions, in vivo fracturing of the ceramic components may occur. In order to minimize this risk, the components were individually examined before delivery. Extremely careful handling is required with ceramic devices, which must not be used if dropped, even in the absence of any apparent damage. Even small scratches or impact points can cause wear and tear or fracture and lead to complications. Cause of fracture can be an overload on the prosthesis, for example through incorrect placement of the ceramic head on the stem taper or a wrong or missing fit between the ceramic head and the stem taper. The use of prosthesis components which are not released by MicroPort for combination with a ceramic component can also lead to the fracture of the implant. The recommended position of the acetabular insert (inclination/ anteversion) must be observed.

Only use a plastic tip to introduce the ceramic devices.

Fracture of ceramic components is a serious complication. Only use a plastic tip to introduce the ceramic devices. Impact according tot he recommended surgical technique. Patients should be advised to report unusual noise and/or sharp pain as both can be an indication of fracture. Decision to revise should not be postponed as ceramic fragments can cause severe damage to surrounding soft tissue and metal components.

Revision outcomes after ceramic fractures can be compromised by the remaining ceramic debris present in the tissue even after careful debridement. Damage has been reported in polyethylene and metal components used in revisions after ceramic fractures. Metal heads should not be used after a ceramic fracture. Surgeons are advised to carefully consider all available implant options on an individual basis. It must be noted that removal of all components including femoral stems and acetabular shells may not prevent accelerated wear due to ceramic debris in the tissue. Partial or complete synovectomy has been recommended by some authors.

The size 28mm Long Neck alumina (Biolox Forte) "Ceramic Femoral Heads" are indicated for use only with titanium alloy femoral stems. All other sizes of the alumina (Biolox Forte) "Ceramic Femoral Heads" and all sizes of the Alumina Matrix Composite Heads ("Biolox Delta Femoral Head") are indicated for use with titanium alloy, cobalt chrome, or MicroPort stainless steel (not available in the U.S. or Canada) femoral stems.

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

NEVER combine modular or hard bearing components made by different manufacturers.

IMPORTANT

Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse 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 inserts are available on the website listed.

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The CE-Marking of Conformity is applied per catalog number and appears on the outer package label, if applicable

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