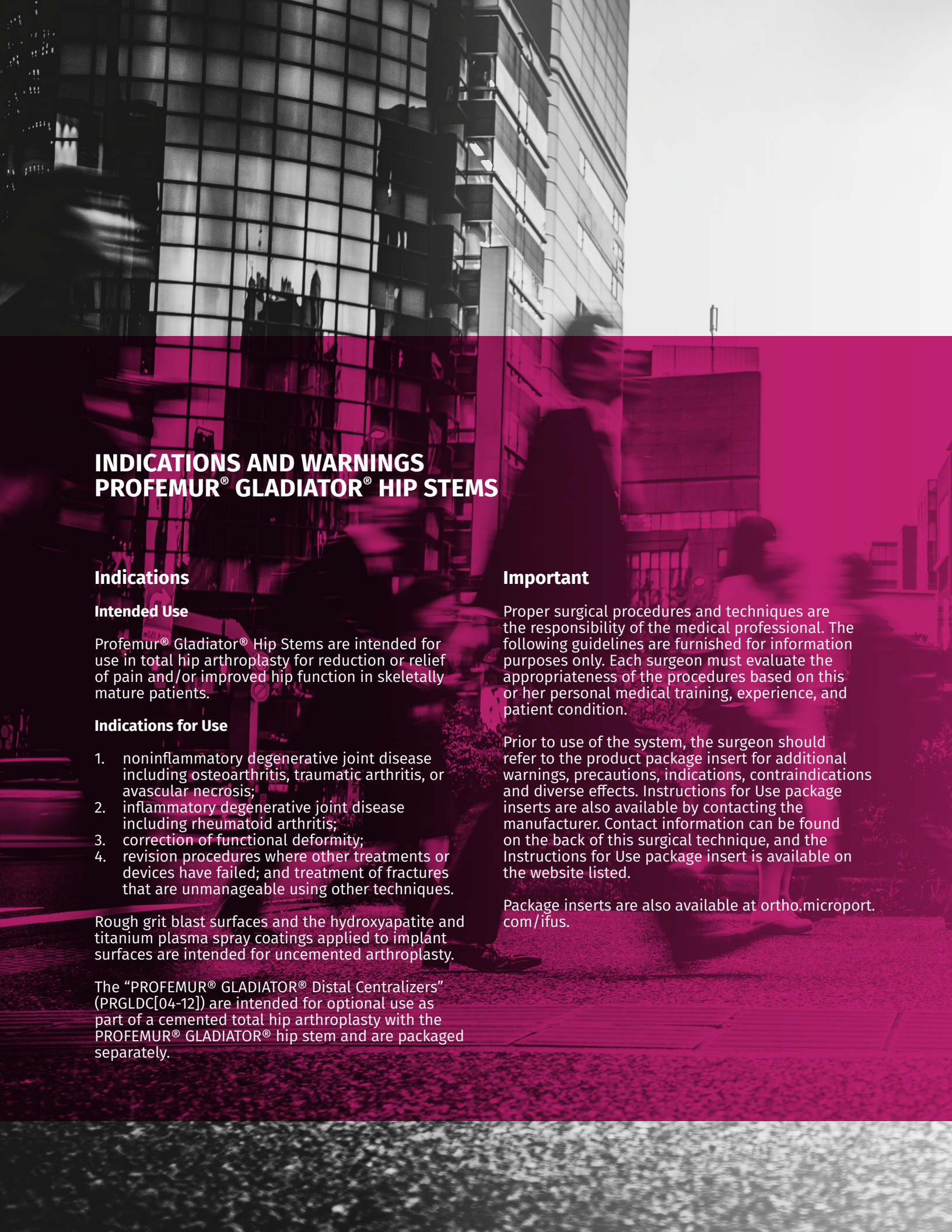
MicroPort

Profemur®

GLADIATOR®

Classic Stems - Surgical Technique



INDICATIONS AND WARNINGS PROFEMUR® GLADIATOR® HIP STEMS

Indications

Intended Use

Profemur® Gladiator® Hip Stems 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. noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. inflammatory degenerative joint disease including rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

Rough grit blast surfaces and the hydroxyapatite and titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.

The “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.

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 system, 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.

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Foreword

The Profemur® Gladiator® hip system 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 system 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:

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Milwaukee, WI

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

William M. Ricci, MD
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Design features

Gladiator® Plasma Stem

Neck Options

Medium neck length, Straight (135º CCD) and Varus 8º (127º CCD) neck angles allowing for multiple head center positions to meet range of anatomical needs

Macro-Features

Vertical grooves are designed for additional rotational stability, while horizontal grooves are designed to evenly distribute load forces

Driving Platform

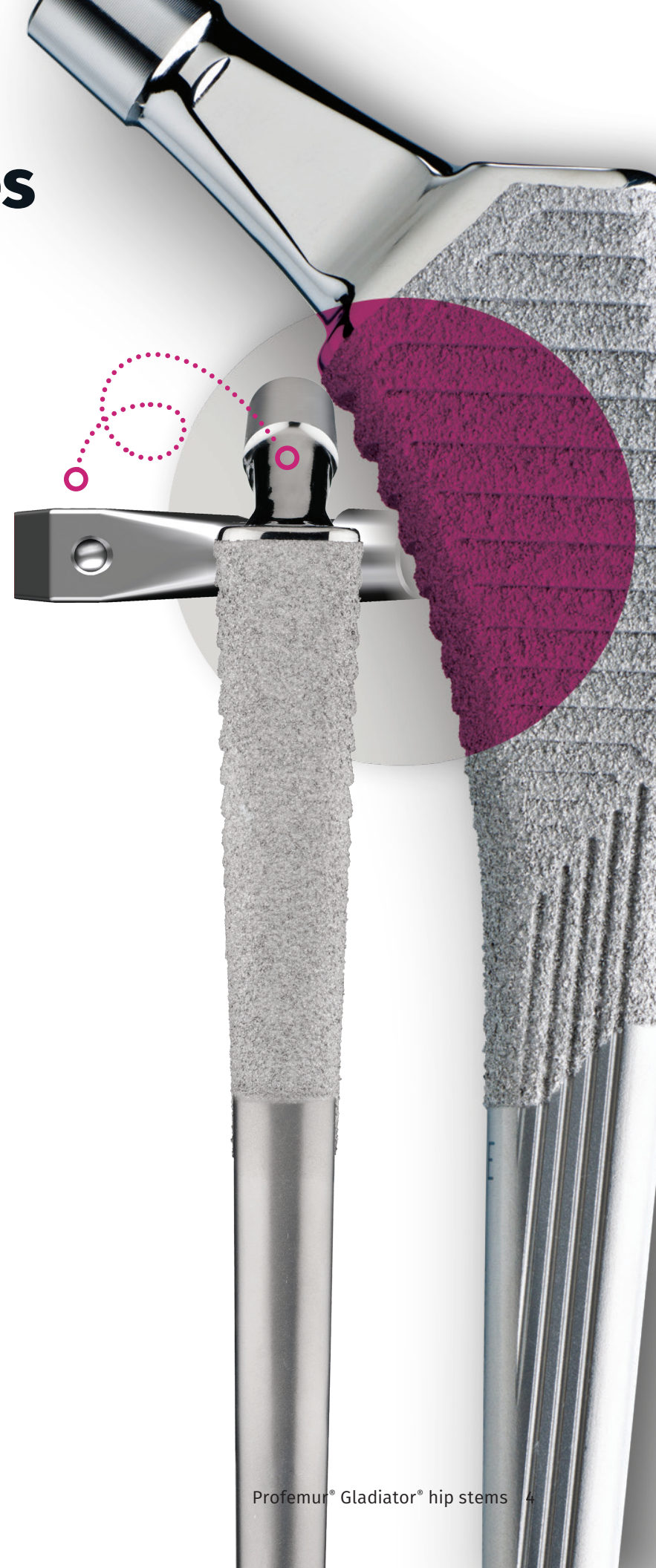
Dimpled driving platform for unidirectional loading during stem insertion

Lateral Shoulder

Reduced profile helps to conserve bone and ease insertion

Plasma Spray

Coating thickness provides 1mm (0.5mm per side) additional press-fit



Design features

Gladiator® HA Collared Stem

Material

HA-Coated stems are made from forged titanium alloy (Ti6Al4V)

Collar

Designed to assist rotational stability and offer protection against subsidence

Lateral shoulder

Reduced profile helps to preserve bone and offers ease of insertion

Macrofeatures

Designed to provide additional rotational stability and maximize compressive loading forces

HA Coating

Designed to enhance bone fixation

Common instrumentation

Utilizes same set of broaches for all stem variants

Sizes

Collared stems are available in sizes 1–10

Design features

Gladiator® Cemented Collared Stem

Collar

Designed to assist rotational stability and offer protection against subsidence

Macrofeatures

Designed to provide additional rotational stability and maximize compressive loading forces

Driving Platform

Slotted driving platform for rotational control during stem insertion

Lateral shoulder

Reduced profile helps to preserve bone and offers ease of insertion

Common instrumentation

Utilizes same set of broaches for all stem versions, providing a 1.5mm (all around) cement mantle built-in

Distal Centralizer

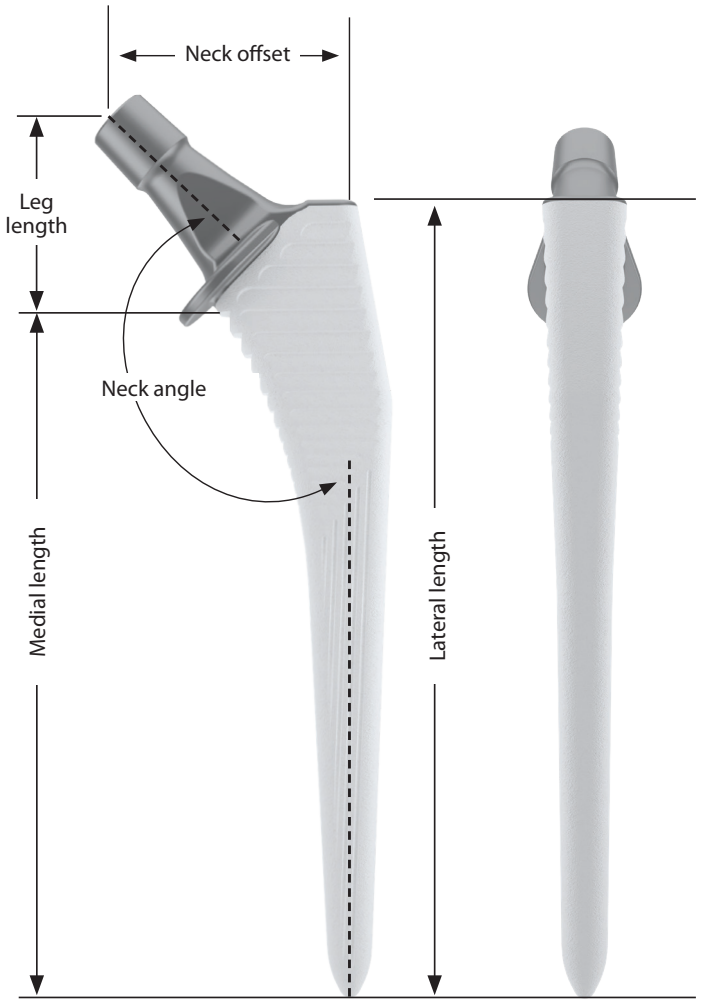
Available for each size of implant for a 1.5mm distal circumferential cement mantle

Note: Centralizers must be ordered separately

General specifications

Gladiator® stems

- Cementless stems are forged from ti-6al-4v titanium alloy
- Cemented Stems are forged from Cobalt Chrome
- Commercially pure titanium plasma spray over proximal region (0.5mm/side) or 65 um HA coating thickness
- M/L width: 30-38mm
- A/P thickness: 14-22mm



Gladiator® hip stems dimensional chart

(Measurements in millimeters)

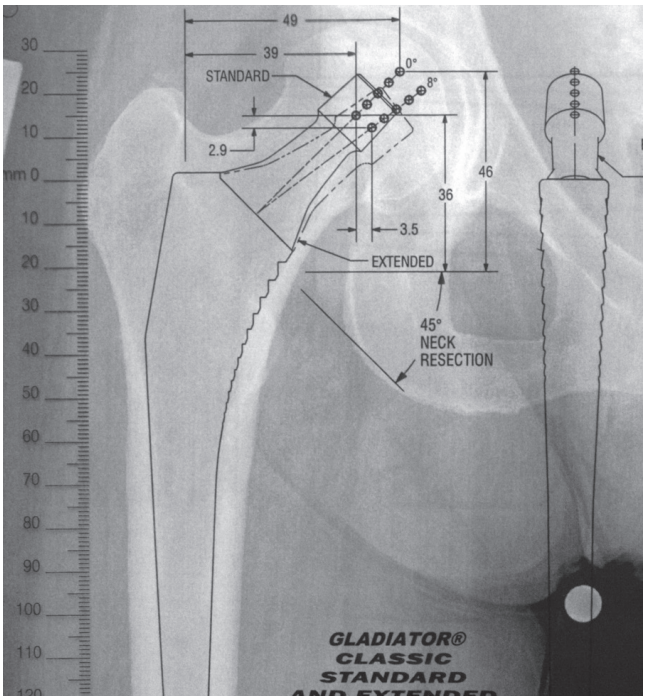
	Size	Neck Measurements		Stem Measurements	
		Leg Length	Neck Offset	Medial Length	Lateral Length
	STRAIGHT (135°)				
Cementless	1	35	40	107	125
	2	35	41	117	135
	3	36	42	122	140
	4	36	43	127	145
	5	36	43	132	150
	6	36	44	137	155
	7	37	45	142	160
	8	37	46	147	165
	9	37	47	152	170
	10	37	48	157	175
Cemented	4	35	43	107	125
	6	35	44	122	140
	8	36	46	132	150
	10	37	47	142	160
	12	37	48	152	170
	VARUS 8° (127°)				
Cementless	1	34	46	107	125
	2	34	47	117	135
	3	35	48	122	140
	4	35	49	127	145
	5	35	49	132	150
	6	35	50	137	155
	7	35	51	142	160
	8	36	52	147	165
	9	36	53	152	170
	10	36	53	157	175
Cemented	4	33	49	107	125
	6	34	50	122	140
	8	35	52	132	150
	10	35	53	142	160
	12	36	54	152	170

Profemur® Gladiator® hip stems dimensional chart

(Measurements in millimeters)

		OFFSET / LEG LENGTH ADJUSTMENT	
Head Size	Neck Length Adjustment	Straight	Varus 8°
X Short	-7	-4.9 / -4.9	-5.6 / -4.2
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

Preoperative planning



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 established, 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. The 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.

Each circle represents the center of rotation for the corresponding head option (Short to XX Long). The circles on the A/P template of the stem illustrate the impact of choosing an 8° varus neck relative to the neutral neck position.

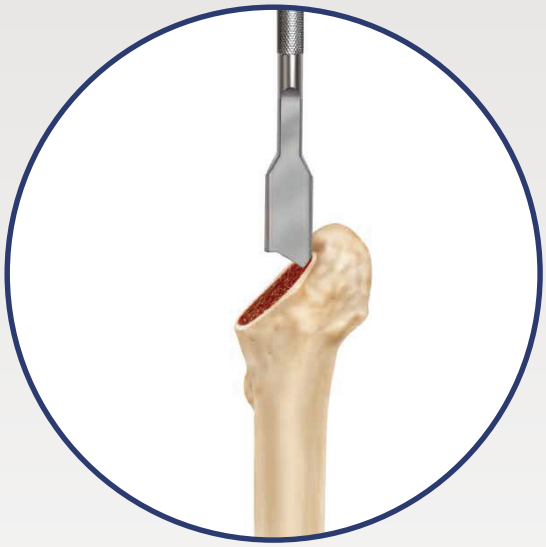
The lateral x-ray illustrates the front to back fill of the implant and the position of the implant relative to the femoral anterior bow. If the anterior bow is high, the implant size may be reduced to minimize the risk of fracture.

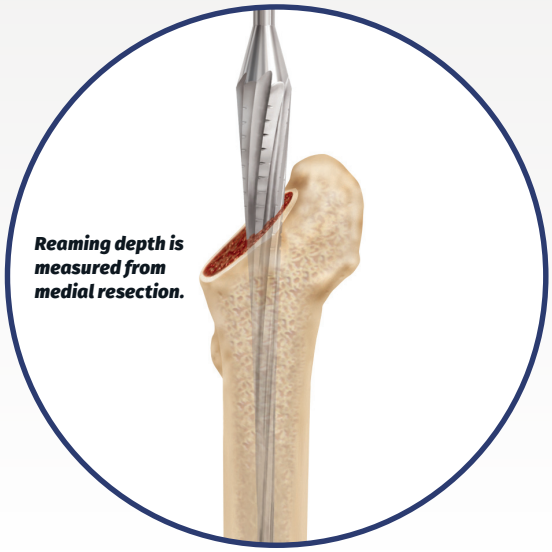
Profemur® Neck Resection Guide
P/N PTRG0410

Profemur® Box Chisel
P/N PRFS0450

Profemur® Gladiator®
Starter Reamer
P/N PRGLREAM

Quick Disconnect T-Handle
P/N K0001016





Surgical technique

Femoral neck osteotomy

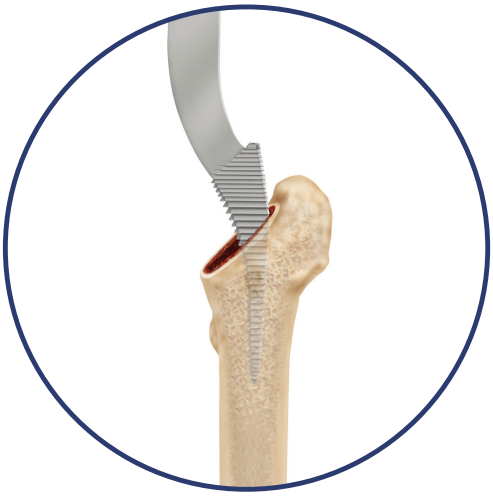
Using the greater trochanter or lesser trochanter as a reference, resect the neck at a 45o angle to the longitudinal axis of the femur. The Profemur® Neck Resection Guide (P/N PTRG0410) is available to help establish the angle of resection.

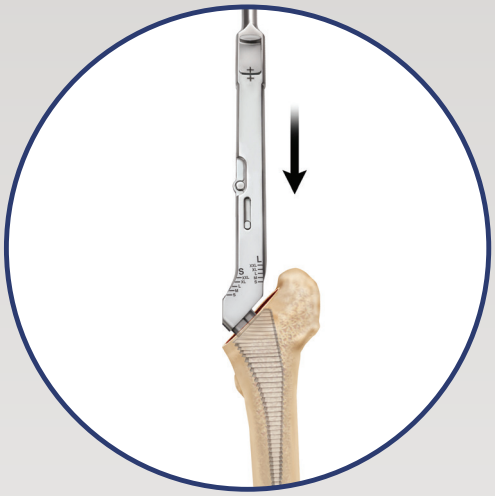
Open the femoral canal

Using the Profemur® Box Chisel (P/N PRFS0450), 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 (P/N PRGLREAM). Machined grooves along the surface of the starter reamer indicate the medial lengths of the corresponding broach sizes and reflect the proper depth at which to ream. Attach the Quick Disconnect T-Handle (P/N K0001016) onto the starter reamer, and ream to the appropriate depth according to preoperative templating. The diameter of the reamer is smaller than the corresponding broach at each groove. By stopping the reamer at the appropriate groove, it is assured that the final shape of the femoral canal will be determined by the broach. Manual reaming of the femur using the T-handle 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 a surgical drill.





Profemur® Gladiator® Starter Broach
P/N PRGLSTBR

T-broach handle
P/N INLNBRHN

Profemur® Gladiator® Broach Size 1
P/N PRGLBR01

Starter broach

Prepare the femoral canal with the Profemur® Gladiator® Starter Broach (P/N PRGLSTBR). Staying centered between the anterior and posterior cortices, impact the starter broach until the top of the teeth rests just at or below the level of the neck resection.

Femoral broaching

Attach the preferred broach handle (the T Broach Handle, P/N BROHANTL, is shown) to the Size 1 Profemur® Gladiator® Broach (P/N PRGLBR01). Using a mallet with short, controlled strokes, begin broaching. Continue broaching until an optimal fit is found. The top of the broaches is equal to the top of the plasma coating.

Sequentially increase the broach sizes while 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. If the surgeon desires, an intraoperative control radiograph can be obtained to confirm correct sizing.

Some notes on broaching for cemented stems:

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

2. Cementless stems have been dimensioned across the M/L width with a 1mm increment between sizes. The size of the broach is equal to the corresponding stem size.

3. Cemented stems are labeled to be implanted using the same broach size, but are smaller than the broaches and the corresponding cementless sizes by 1.5mm/side. This will prepare a uniform 1.5mm cement mantle thickness around the stem

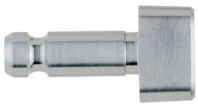
Stem Size	Broach Used to Implant
4	4
6	6
8	8
10	10
12	12

Potential differences between broached 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.

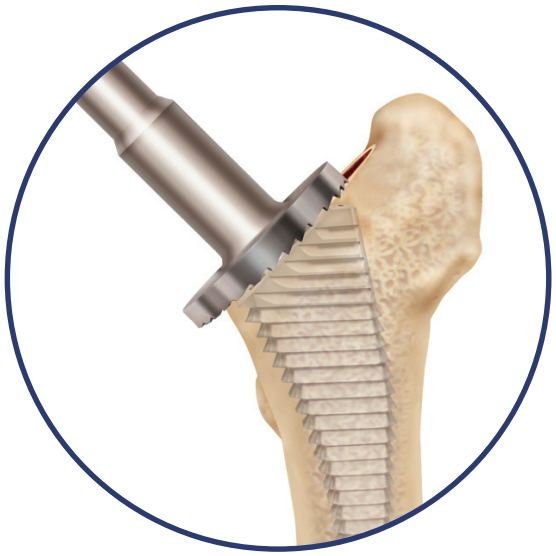
If a broach smaller than the size templated becomes tight, hard bone at the lateral femoral neck may be pushing the broach into varus. Use the lateral edge of the broach to restore a neutral position. Additional broaching may be necessary.

If a broach is going in straight and still becomes tight with sizes smaller than 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.



Centralizer Post
P/N PRGLPOST

Calcar Planer
P/N 4700CP0000

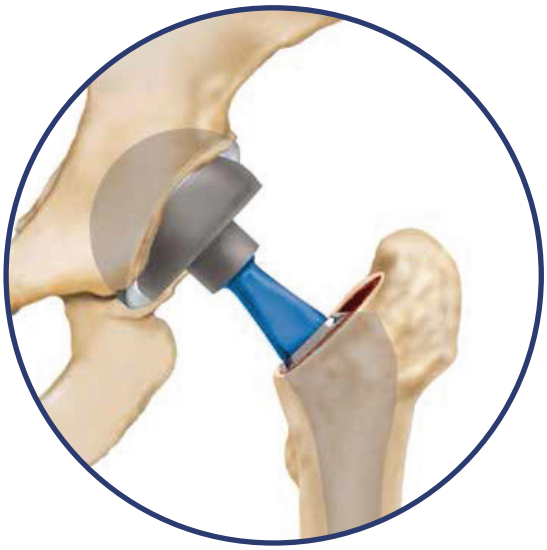


Calcar planing

Instruments are provided for the purpose of calcar planing when implanting one of the collared versions of the Profemur® Gladiator® stems.

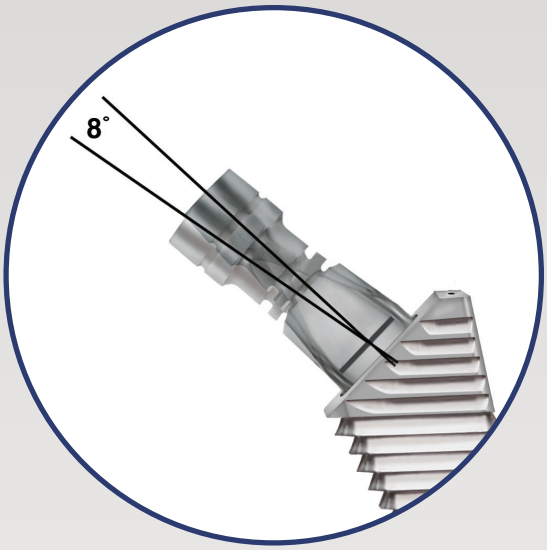
The surgeon may choose to utilize the calcar planer even though the stem to be implanted is collarless. The calcar planer provides a reliable, effective, and accurate cutting instrument for the removal of hard calcar bone. To utilize, the fully seated broach should rest just below the level of the neck resection. Insert the Centralizer Post (P/N PRGLPOST) into the modular neck pocket of the fully seated broach.

Attach the Calcar Planer (P/N 4700CP0000) to a drill and load onto the centralizer post. 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 proximal surface of the broach. Should the teeth become clogged, they can be cleared by flushing with sterile water.



Trial reduction

Select the appropriate Profemur® Gladiator® Classic Metal Trial Neck (P/Ns PRCLSTMN Standard and PRCLEXMN Extended) and trial head (not included in Kit PRGLKIT1) and perform a trial reduction. Profemur® Gladiator® Classic Metal Trial Necks are not equivalent to the length of the standard plastic Profemur® neck trials, but are instead of a mid-length that is between short and long. Once a well-balanced hip has been created with a trial head and trial neck, remove the broach.



Summary of Profemur® Gladiator® neck angle options

- Straight (135°) necks create a neutral neck axis.
- Varus 8° necks decrease the inclination angle to 127°; the femoral head shifts medially and inferiorly; leg length is shortened; offset is increased.
- To ensure proper orientation of the Profemur® Gladiator® Classic Extended Metal Neck Trial, the side of the trial with “MEDIAL” laser-marked on it should be oriented to the medial calcar side.

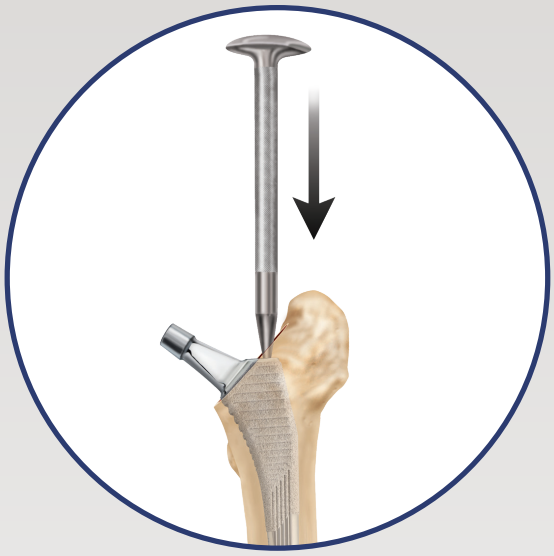
Profemur® Gladiator® Classic Standard Metal Trial Neck P/N PRCLSTMN

Profemur® Gladiator® Classic Extended Metal Trial Neck P/N PRCLEXMN

Final Stem Impactor
P/N PPF60200

Collared Final Stem Impactor
P/N PRCLIMPT

Modular Neck Insert
P/N 20070050



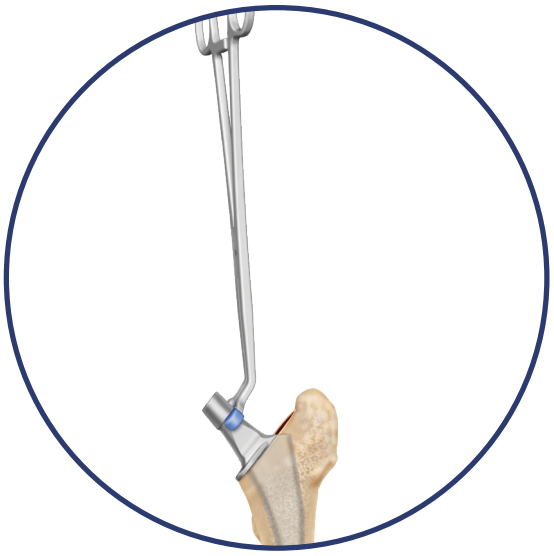
Stem insertion - cementless

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 (see Bone Cement and Accessories Ordering Information section) 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.

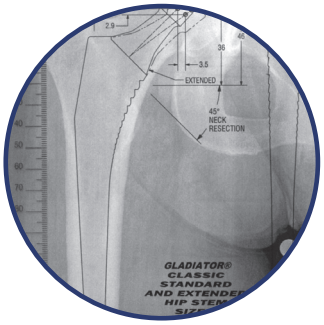
Head assembly

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.

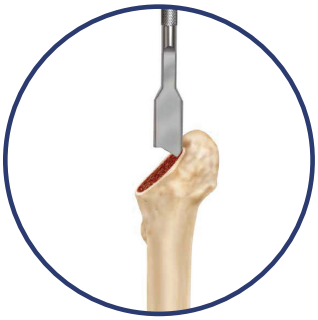
Position the leg such that the knee is supported by an assistant on the opposite side of the table. By resting the patient's knee against the mid-section of the assistant, this will provide counter-force against the mallet blows to ensure the impaction load transfer to the neck junction.

Technique overview

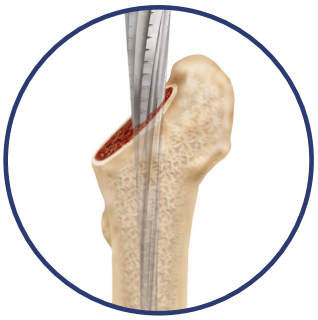


1. X-ray

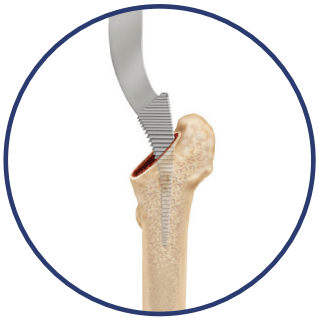
2. Femoral neck osteotomy



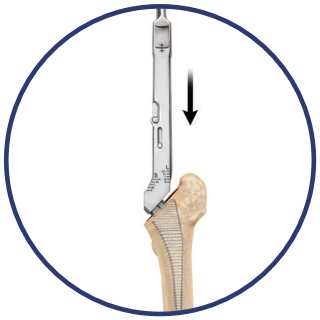
3. Open the femoral canal



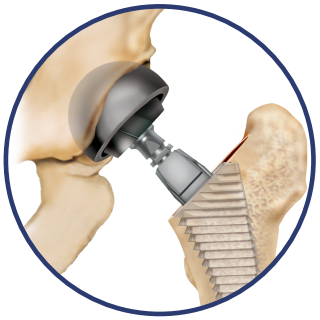
4. Starter reamer



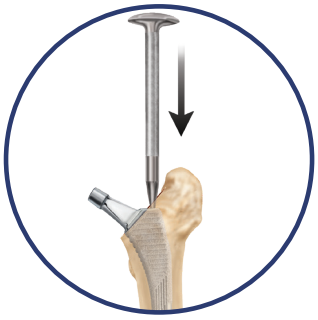
5. Starter broach



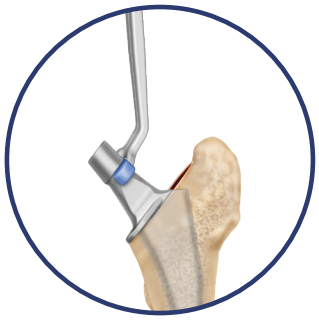
6. Femoral broaching



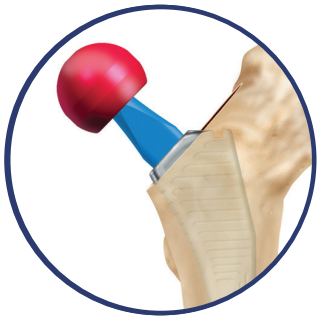
7. Trial reduction



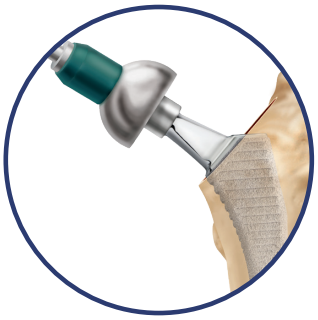
8. Stem insertion



9. Stem insertion - cemented



10. Final trial reduction



11. Implant assembly

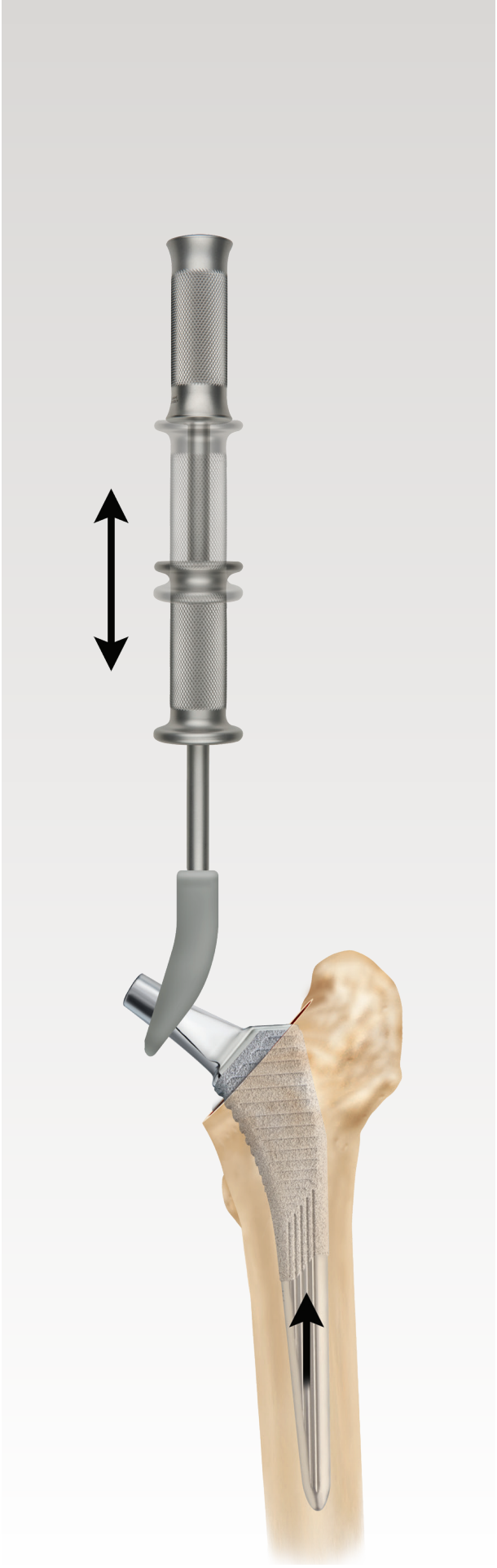
Implant removal

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.



Universal Stem Extractor
P/N 4700SE05

Slap Hammer
P/N 4700SH0000

MicroPort Orthopedics Inc.
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microportortho.com

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