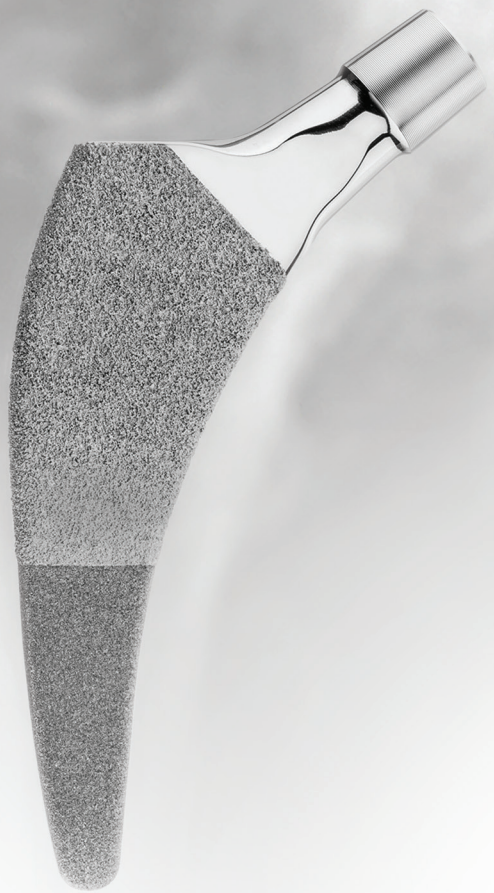
Profemur® Preserve

Hip System: Classic and Modular Stems

Surgical Technique



MicroPort Orthopedics

Full Function, Faster®

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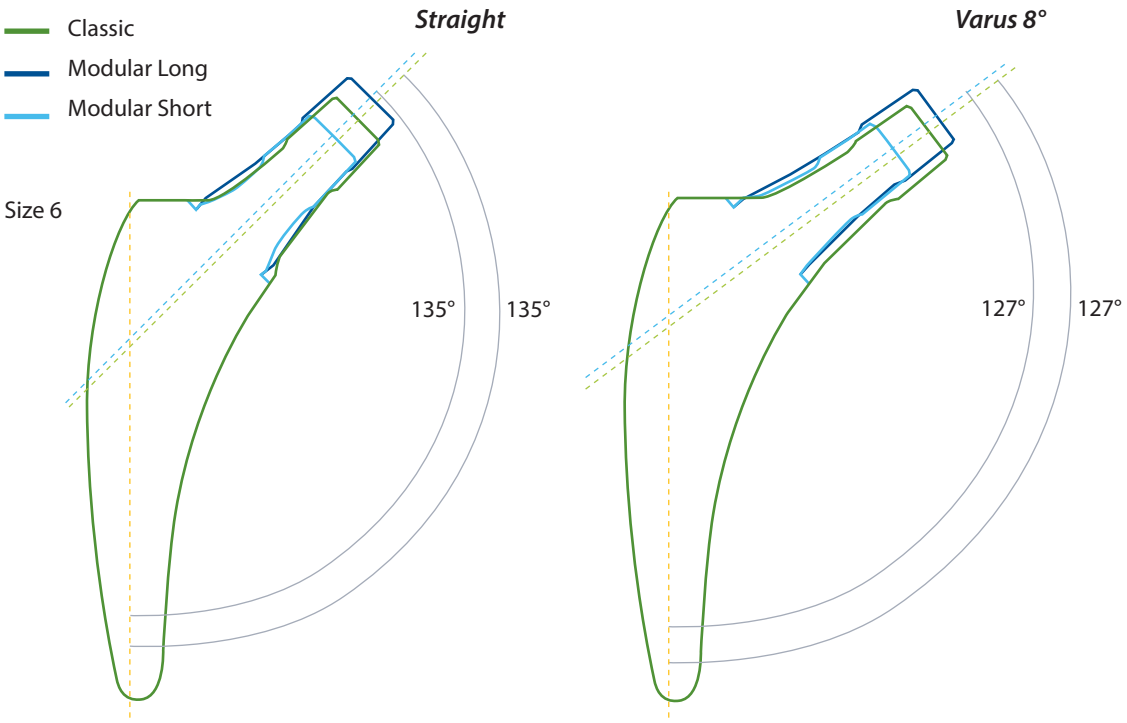
MicroPort Orthopedics recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical 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.

Chapter 1

Design Rationale

Stem Geometry



The Profemur® Preserve Hip System provides stability through its "tri-taper" stem design. Fixation is established using a "taper wedge" that has shown long term clinical success in uncemented stems[1,2]. Secondary fixation is achieved via the trapezoidal cross-section[3], the third taper of the "tri-taper" design that contributes to stability.

Since the Profemur® Preserve stem is shorter compared to conventional stems, its design allows for greater bone conservation during total hip arthroplasty. Less bone is removed during primary THA, and in the event that a revision surgery is needed, more distal bone stock is available. In addition, the reduced lateral shoulder and curved distal geometry combined with the shorter overall length encourages less tissue disruption during broaching and stem insertion.

To maximize the head center coverage, the Profemur® Preserve Classic Stem design team reviewed and templated nearly 1,000 hip arthroplasty x-rays from around the world to determine the optimal neck lengths and CCD angles. The resulting system has 93% head center coverage[4] while using only three neck lengths at 135˚ (Straight) and 127˚ (Varus 8˚) CCD angles. Profemur® Preserve Modular stems allow for intraoperative versatility to address soft tissue tension as needed[5] by offering multiple length and version options.

[1] McLaughlin JR, Lee KR. Total hip arthroplasty with an uncemented tapered femoral component. J Bone Joint surg Am. 2008 Jun; 90(6): 1290-6.

[2] Parvizi J, Keisu KS, Hozack WJ, Sharkey PF, Rothman RH. Primary total hip arthroplasty with an uncemented femoral component: a long-term study of the Taperloc stem. J Arthroplasty. 2004; 19(2):151-6.

[3] Greenwald RM, Wang Y, Rasmussen GL. Effects of stem cross sectional shape on torsional micromotion and migration in an uncemented femoral stem. 45th Annual Meeting, Orthopaedic Research Society, February 1-4, 1999, Anaheim, California.

[4] MicroPort Orthopedics Publication 010985 - Profemur® Preserve Classic Design Rationale, August 2015.

[5] Traina F, De Clerico M, Biondi F, Pilla F, Tassinari E, Toni A. Sex differences in hip morphology: is stem modularity effective for total hip replacement?; J Bone Joint Surg Am 2009 Nov; 91(6):121-8.

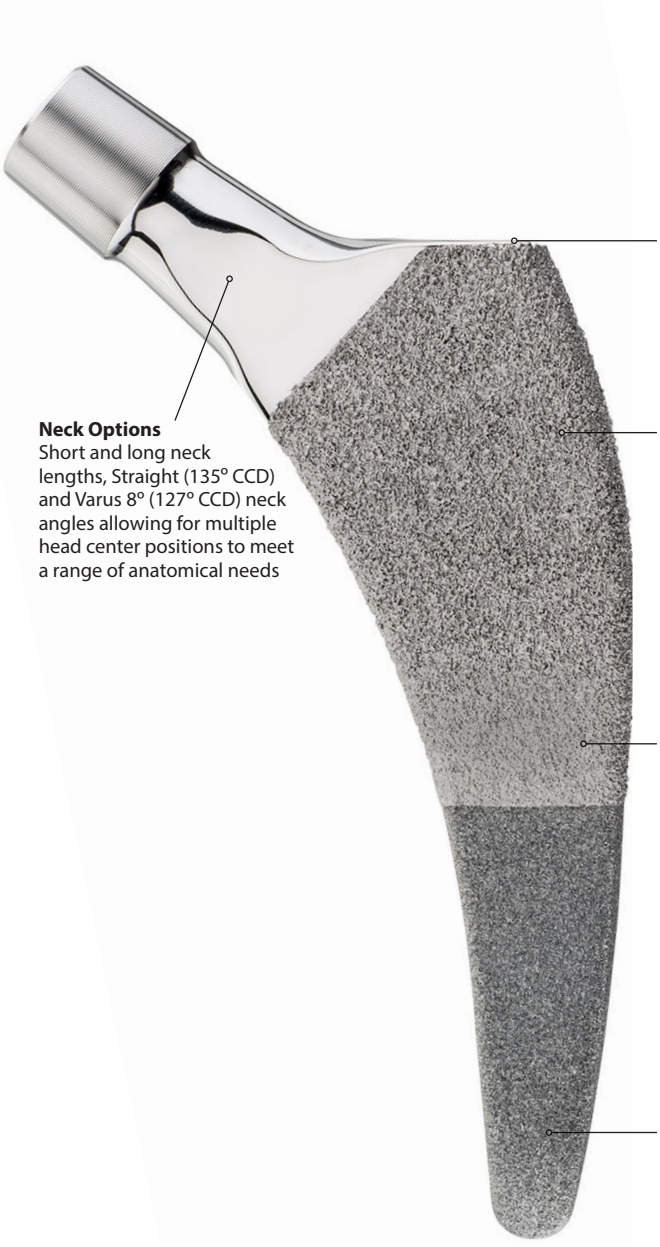
Chapter 2

Product Information

Profemur® Preserve Classic Design Features

Abbreviated Technique: Broach Only	
Broach to templated size	
Implant size corresponding to broach size	
Ordering Information	
Templates	PPRCXR15
Surgical Technique	010984
Instrument Kits	PPREKIT1 (Core instruments) PPREKIT2 (Classic trial necks) PRCLIMPT (Stem Inserter) SPBHKIT1 (In-line broach handles)
Implants	PPREKITB (Classic stems)
Sizes	
Stem	1 - 12

For additional risk information, please consult the Instructions for Use package insert.



Neck Options
Short and long neck lengths, Straight (135° CCD) and Varus 8° (127° CCD) neck angles allowing for multiple head center positions to meet a range of anatomical needs

Driving Platform
Dimple and oval slot designed for unidirectional loading and rotational control during stem insertion, respectively

Lateral Shoulder
Reduced material helps to conserve bone and ease insertion

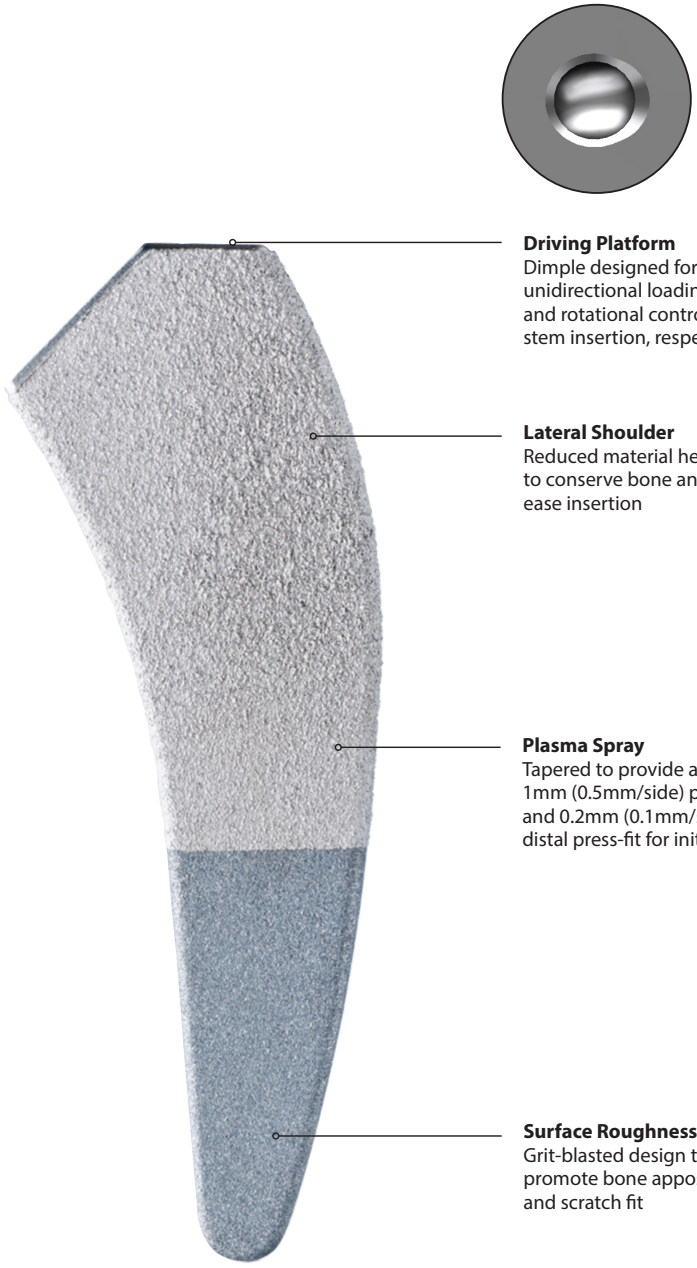
Plasma Spray
Tapered spray to provide additional 1mm (0.5mm/side) proximal and 0.2mm (0.1mm/side) distal press-fit to assist initial stability

Surface Roughness
Grit-blasted design to promote bone apposition and scratch fit

Profemur® Preserve Modular Design Features

Abbreviated Technique: Broach Only	
Broach to templated size	
Implant size corresponding to broach size	
Ordering Information	
Templates	PPREXR15
Surgical Technique	010984
Instrument Kits	PPREKIT1 (Core Instruments) PRGIKIT1 (Includes plastic trial necks, broach handles)
Implants	PPREKITA (Modular stems) COCRKITB (Modular necks)
Sizes	
Stem	1 - 12

For additional risk information, please consult the Instructions for Use package insert.



Driving Platform
Dimple designed for unidirectional loading and rotational control during stem insertion, respectively

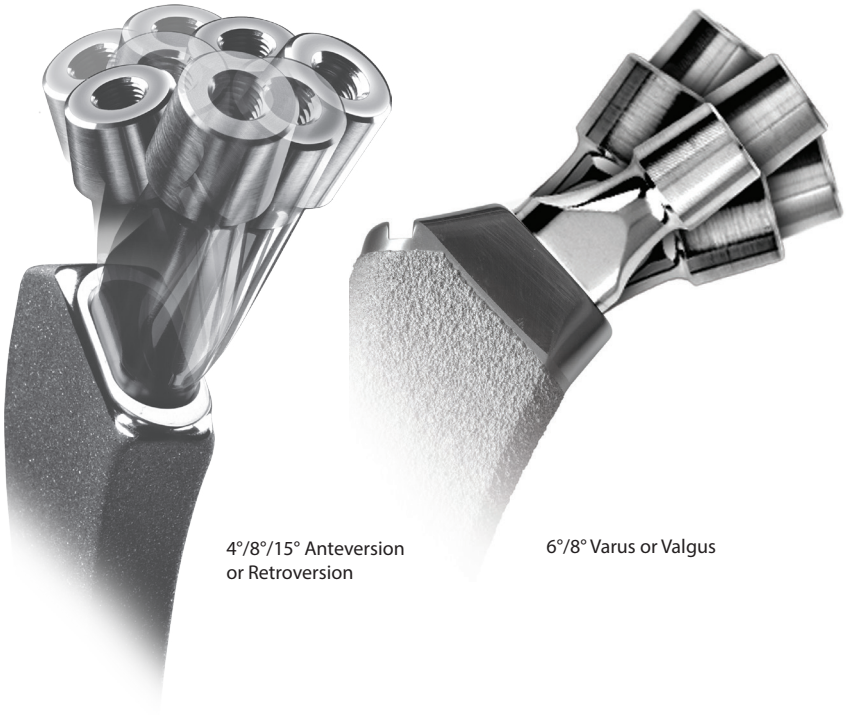
Lateral Shoulder
Reduced material helps to conserve bone and ease insertion

Plasma Spray
Tapered to provide additional 1mm (0.5mm/side) proximal and 0.2mm (0.1mm/side) distal press-fit for initial stability

Surface Roughness
Grit-blasted design to promote bone apposition and scratch fit

Profemur® Preserve Modular Necks Design

- Cobalt Chrome Material
- Varus Neck Angle: 127°
- Neutral Neck Angle: 135°
- Valgus Neck Angle: 143°



4°/8°/15° Anteversion or Retroversion

6°/8° Varus or Valgus

Dimensional Chart (mm)

Type	Length Options
Neutral	Short Long
Varus/Valgus	Short
Ante/Retro 8 Degree	Short Long
Ante/Retro 15 Degree	Short Long
Ante/Retro - Varus/Valgus 1	Short Long
Ante/Retro - Varus/Valgus 2	Short Long

Profemur® Preserve Stems - General Specifications

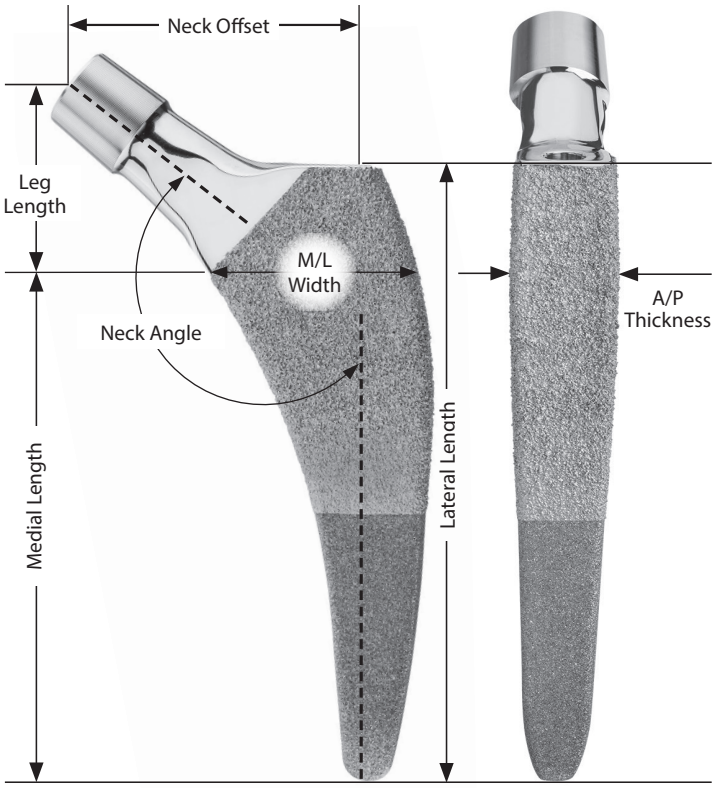
- Stems are made of titanium alloy
- Commercially-pure titanium plasma spray over proximal (0.5mm/side) and distal (0.1mm/side) regions
- M/L Width: 29 - 38mm
- A/P Thickness: 13 - 15mm

Profemur® Preserve Hip Stems Dimensional Chart

(Measurements in millimeters)

Size	Modular Short Neck		Modular Long Neck		Classic Neck		Stem Measurements			
	Leg Length	Neck Offset	Leg Length	Neck Offset	Leg Length	Neck Offset	Med. Length	M/L Width	A/P Thickness	Lat. Length
Straight (135°)										
1	26	33	33	41	27	35	75	29	13	92
2	26	34	33	42	27	36	75	30	13	92
3	26	34	33	44	27	36	75	30	13	92
4	26	35	33	45	27	37	75	31	13	92
5	26	36	33	45	29	40	78	32	14	95
6	26	36	33	47	29	41	81	33	14	98
7	26	37	33	47	29	41	84	33	14	101
8	26	37	33	41	29	42	87	34	14	104
9	26	38	33	42	32	45	90	35	14	107
10	26	39	33	44	32	46	93	36	14	110
11	26	39	33	45	32	47	96	37	15	113
12	26	40	33	45	32	47	99	38	15	116
Varus 8° (127°)										
1	24	36	30	45	24	41	75	29	13	92
2	24	37	30	46	24	41	75	30	13	92
3	24	37	30	48	24	42	75	30	13	92
4	24	38	30	49	24	42	75	31	13	92
5	24	39	30	49	27	46	78	32	14	95
6	24	39	30	51	27	46	81	33	14	98
7	24	40	30	51	27	47	84	33	14	101
8	24	40	30	45	27	47	87	34	14	104
9	24	41	30	46	29	51	90	35	14	107
10	24	42	30	48	29	51	93	36	14	110
11	24	42	30	49	29	52	96	37	15	113
12	24	43	30	49	29	53	99	38	15	116

Offset and leg length is based on a +0 head.



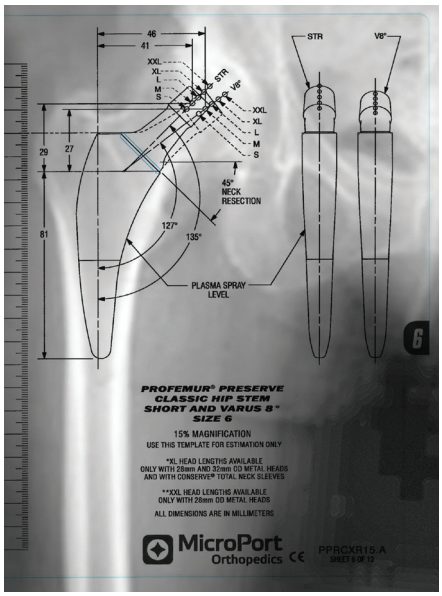
Head Center Adjustment Chart

(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 3

Preoperative Planning



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

Accurate pre-operative templating requires good quality standardized radiographs of the pelvis and operative hip. To 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 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 a modular short neck with the corresponding head option (Short to XX Long). Each square represents the center of rotation for a modular long neck with the corresponding head option (Short to XX Long). 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.

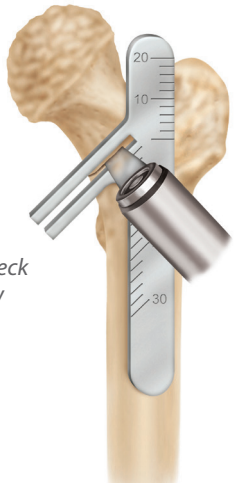
NOTE: AR/VV necks can also affect neck position by 6˚varus/valgus.

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.

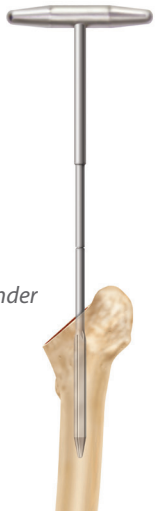
Chapter 4

Surgical Technique



Femoral Neck Osteotomy

Open the Femoral Canal



Canal Finder

Lateralizing Rasp

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. The Profemur® Neck Resection Guide (P/N PTRG0410, not included in kit PPREKIT1) 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.

Canal Finder (Optional)

Enter the femoral canal with the Profemur® Preserve Canal Finder (P/N 20070186). A machined groove around the middle of the shaft provides the surgeon with the proper reaming depth. The length of the instrument distal from this groove represents the length of the piloted broaches, while the diameter matches that of the distal pilots on the piloted broaches. The canal finder is designed with a T-handle to avoid over-reaming the canal, to maintain alignment control, and to minimize the amount of heat generated during use.

Lateralizing Rasp

Prepare the metaphyseal region of the femoral canal with the Lateralizing Rasp (P/N 20070185). The shaft of this instrument has aggressive teeth and is curved with a radius between those of the medial and lateral surfaces of the Profemur® Preserve implants.

Profemur® Neck Resection Guide (P/N PTRG0410)

Profemur® Box Chisel P/N PRFS0450

Profemur® Preserve® Canal Finder P/N 20070186

Lateralizing Rasp P/N 20070185

Starter Broach

Piloted Broach

Femoral Broaching

Starter Broach and Piloted Modular Broach

Prepare the femoral canal with the Profemur® Preserve Starter Broach (P/N PRPRSTBR) or Profemur® Preserve Piloted Modular Broach (P/N PRPRPB01). For additional alignment during this initial stage of the broaching process, the surgeon may choose to utilize a piloted version of the size 1 broach. Staying centered between the anterior and posterior cortices, impact the starter or piloted modular broach until the top of the teeth rest just at or below the level of the neck resection.

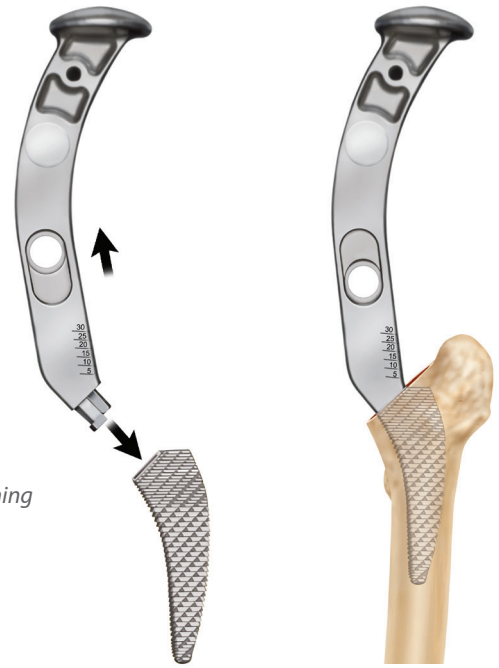
Femoral Broaching

Attach the preferred broach handle (P/N PPW38078 is shown) to the appropriate size Profemur® Preserve broach (P/Ns PPREBR01 - PPREBR03 and PRPRBR04 - PRPRBR12). The broaches are designed to engage any Profemur® style broach handle. Starting with the modular broach that is one size larger than the starter or piloted modular broach, begin broaching using a mallet with short, controlled strokes. The top of the broach teeth is equal to the top of the plasma spray coating.

Profemur® Preserve Starter Broach P/N PRPRSTBR

Profemur® Preserve Piloted Modular Broach P/N PRPRPB01

Profemur® Broach Handle Broach P/N PPW38078



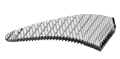
Femoral Broaching

Sequentially increase the broach sizes while broaching. 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, the broach handle can be rotated relative to the femur. With proper cortical contact, the broach should not move. 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.

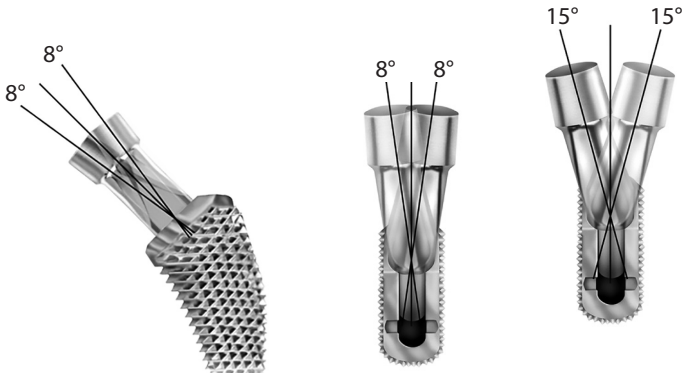
Potential Differences Between Broached and Templated Sizes:

1. 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.
2. 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.
3. 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.



Profemur® Preserve Broach Size 1
P/N PPREBR01

Trial Reduction



Trial Reduction

Select the appropriate trial neck (P/Ns APA11102 - APA11152 not included in kit PPREKIT1) and trial head (P/Ns APA02121 - APA02148, not included in kit PPREKIT1) and perform a trial reduction. Once a well-balanced hip has been created with a trial head and trial neck, remove the broach.

NOTE: When implanting a Profemur® Preserve Classic, six dedicated trial necks have to be used (PPRTNG1S, PPRTNG1E, PPRTNG2S, PPRTNG2E, PPRTNG3S and PPRTNG3E). Those specific trial necks are included in kit PPREKIT2.

Brief Summary of Modular Neck Options

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.

»» Straight necks create a neutral neck axis (135˚)

»» Varus necks decrease the inclination angle to 127˚; 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.

Brief Summary of Classic Neck Options

The trial necks for the Profemur® Preserve Classic are specific to the implant size and therefore have to match the size of the in situ broach. Clear identification for the sizing is engraved on the trial neck, in addition to color coding. The proximal groove below the round trunnion indicates the proximal/lateral side of the trial neck. Ensure proper positioning of the trial neck with visual and tactile confirmation.

»» When broach sizes 1 to 4 are implanted, necks PRTNG1S and PPRTNG1E can be selected to replicate a neutral neck axis (135°) or a varus neck axis (127°), respectively.

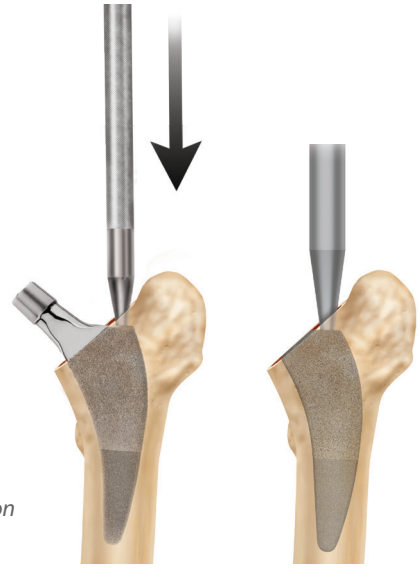
»» When broach sizes 5 to 8 are implanted, necks PRTNG2S and PPRTNG2E can be selected to replicate a neutral neck axis (135°) or a varus neck axis (127°), respectively.

»» When broach sizes 9 to 12 are implanted, necks PRTNG3S and PPRTNG3E can be selected to replicate a neutral neck axis (135°) or a varus neck axis (127°), respectively.

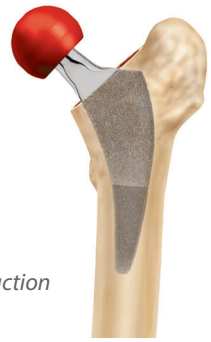
Profemur® Preserve Classic Trial Necks Sizes 1-4 P/N PPRTNG1S and PPRTNG1E

Profemur® Preserve Classic Trial Necks Sizes 5-8 P/N PPRTNG2S and PPRTNG2E

Profemur® Preserve Classic Trial Necks Sizes 9-12 P/N PPRTNG3S and P/N PPRTNG3E



Stem Insertion



Final Trial Reduction

Stem Insertion

Insert the femoral implant into the canal and seat it as far as possible by hand while maintaining proper version. Place the Final Stem Impactor (P/N PPF60200) into the dimple on the proximal face and, using a mallet, fully seat the implant using short, controlled strokes.

For Classic stems, the Profemur® Classic Stem Inserter (P/N PRCLIMPT, order separately) is also available to provide rotation control during impaction. Place the tip of the impactor into the impaction feature on the proximal face and, with a mallet, fully seat the implant using short, controlled strokes.

Modular Stem Insertion (Optional)

For modular stems, the Profemur® Modular Pocket Stem Inserter (P/N PRMOD451) is also included in the Profemur® Preserve instrumentation. The Modular Pocket Stem Inserter is designed to fit onto every Profemur® broach handle and engages the modular neck pocket of any Profemur® Stem. Upon impacting, forces are translated into the implant at the base of the modular neck pocket, with the black plastic sleeve protecting the inside pocket surfaces.

Typically, the implant is seated with the base of the polished neck at the resection cut. For the Profemur® Preserve, the implant may sit 1-2 mm more 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.

Final Trial Reduction

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

CAUTION: Do not use metal trial necks with the modular implant. Metal trial necks are only to be used with broaches since they may damage the neck taper. Only plastic trial necks (available in PRGIKIT1) should be used for trial reductions with the implant.

Final Stem Impactor
P/N PPF60200

Profemur® Classic Stem Inserter
P/N PRCLIMPT

Profemur® Modular Pocket Stem Inserter
P/N PRMOD451

Implant Assembly

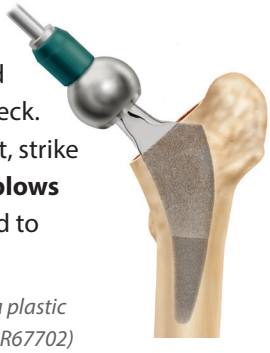
To properly assemble and impact a Profemur® modular neck, the following procedure is recommended:

STEP A. Suction any fluid from the stem impact pocket. Ensure that both the stem and neck are clean and dry prior to assembly.

STEP B. Insert the oval end of the appropriate femoral neck implant into the femoral stem pocket.

STEP C. 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 D. 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.

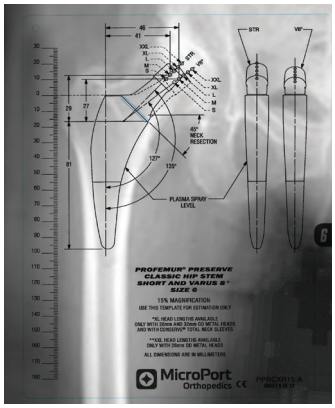


NOTE: *Place a femoral head impactor with a plastic impaction tip (such as P/N 4400FI0000 or PPR67702) on ceramic head, and align the impactor with the femoral neck axis of the stem implant. With a moderate tap of the hammer in an axial direction, firmly impact the ceramic head until it is fully seated.*

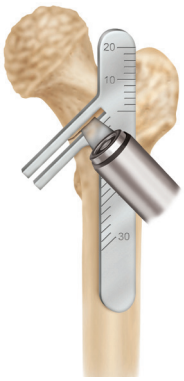
NOTE: If using a Profemur® Classic Stem, affix the femoral head to the stem and impact as instructed.

Chapter 5

Technique Overview



1. X-ray



2. Femoral Neck Osteotomy

3. Open the Femoral Canal

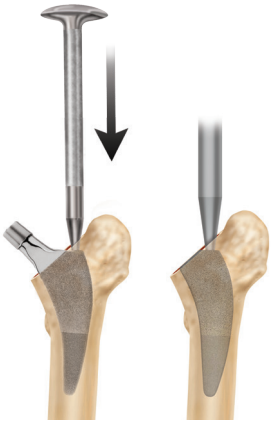
4. Canal Finder *(optional)*

5. Lateralizing Rasp

6. Starter Broach and Piloted Modular Broach

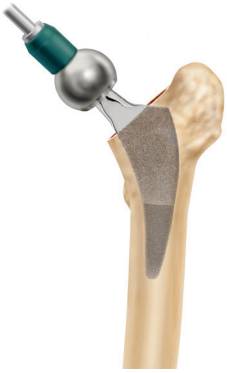
7. Femoral Broaching

8. Trial Reduction



9. Stem Insertion

10. Final Trial Reduction



11. Implant Assembly

Chapter 6

Implant Removal

Femoral Stem Removal - Classic Option

Stem Removal

Should the removal of a Profemur® Classic Stem become necessary, the 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.

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

Femoral Stem Removal - Modular Option

Modular Neck Removal

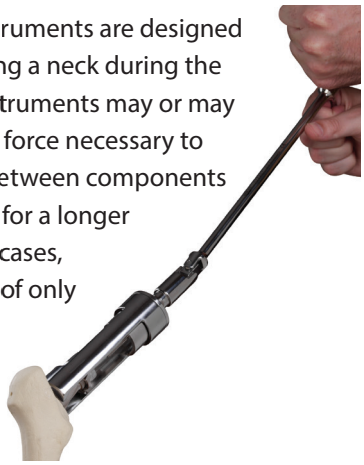
Should it be necessary, a Profemur® hip stem can be removed in the following manner.

STEP A. The femoral head is removed by placing an osteotome or bone punch on the underside of the femoral head and applying mallet blows upward until the femoral head is removed. With the femoral head removed, thread the 12/14 Adapter (P/N APA00003) over the round taper end of the modular neck.

STEP B. Place the Head/Neck Extractor (P/N APA00001) over the 12/14 adaptor and modular neck and hand tighten the hex end of the shaft until the base of the extractor rests on the stem, while the fork of the extractor rests under the rim of the adaptor.

CAUTION: The base of the extractor must rest on the top surface of the stem's modular neck pocket, and not on the resected bone.

STEP C. Attach the Spanner Handle (P/N APA00005) to the hex end of the extractor and rotate clockwise until the neck taper disengages. The Tommy Bar (P/N APA00006) can be inserted into the end of the spanner handle for even greater leverage.



Please note that these instruments are designed for the purpose of removing a neck during the primary surgery. These instruments may or may not be able to provide the force necessary to disengage a connection between components that have been implanted for a longer period of time. In revision cases, removal and replacement of only the modular neck is contraindicated.

Modular Stem Removal

The thread at the base of the Profemur® stem's modular neck pocket can now be accessed to remove the stem. Insert the Femoral Stem Extractor (P/N PPR67688) into the modular neck pocket and tighten the threaded shaft by hand, firmly seating the shaft via the use of the Hex Screwdriver (P/N PP275400). Using the slide hammer, create extraction forces onto the underside of the shaft using repetitive upward blows 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.

NOTE: Modular extraction instruments are included in PRGIKIT1.

12/14 Adapter
P/N APA00003

Head/Neck Extractor
P/N APA00001

Spanner Handle
P/N APA00005

Tommy Bar
P/N APA00006

Femoral Stem Extractor
P/N PPR67688

Hex Screwdriver
P/N PP275400

Chapter 7

Ordering Information

Profemur® Preserve Classic Stems

PPREKITB

Catalog No.	Description	Stem Size
PPRCLS01	Classic Straight Stem	1
PPRCLS02	Classic Straight Stem	2
PPRCLS03	Classic Straight Stem	3
PPRCLS04	Classic Straight Stem	4
PPRCLS05	Classic Straight Stem	5
PPRCLS06	Classic Straight Stem	6
PPRCLS07	Classic Straight Stem	7
PPRCLS08	Classic Straight Stem	8
PPRCLS09	Classic Straight Stem	9
PPRCLS10	Classic Straight Stem	10
PPRCLS11	Classic Straight Stem	11
PPRCLS12	Classic Straight Stem	12
PPRCLE01	Classic Varus 8˚Stem	1
PPRCLE02	Classic Varus 8˚Stem	2
PPRCLE03	Classic Varus 8˚Stem	3
PPRCLE04	Classic Varus 8˚Stem	4
PPRCLE05	Classic Varus 8˚Stem	5
PPRCLE06	Classic Varus 8˚Stem	6
PPRCLE07	Classic Varus 8˚Stem	7
PPRCLE08	Classic Varus 8˚Stem	8
PPRCLE09	Classic Varus 8˚Stem	9
PPRCLE10	Classic Varus 8˚Stem	10
PPRCLE11	Classic Varus 8˚Stem	11
PPRCLE12	Classic Varus 8˚Stem	12

Profemur® Preserve Classic Trial Necks Kit

PPREKIT2

Catalog No.	Description
PPRTNG1S	Classic Trial Necks sizes 1-4 Straight
PPRTNG1E	Classic Trial Necks sizes 1-4 Varus 8°
PPRTNG2S	Classic Trial Necks sizes 5-8 Straight
PPRTNG2E	Classic Trial Necks sizes 5-8 Varus 8°
PPRTNG3S	Classic Trial Necks sizes 9-12 Straight
PPRTNG3E	Classic Trial Necks sizes 9-12 Varus 8°

Profemur® Preserve Stems

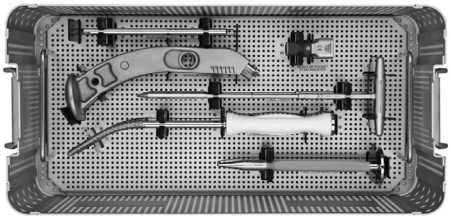
PPREKITA

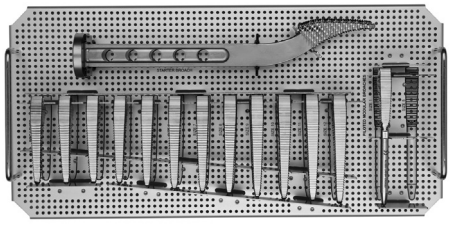
Catalog No.	Description	Size
PPRE0001	Profemur® Preserve Stem	Size 1
PPRE0002	Profemur® Preserve Stem	Size 2
PPRE0003	Profemur® Preserve Stem	Size 3
PRPR0004	Profemur® Preserve Stem	Size 4
PRPR0005	Profemur® Preserve Stem	Size 5
PRPR0006	Profemur® Preserve Stem	Size 6
PRPR0007	Profemur® Preserve Stem	Size 7
PRPR0008	Profemur® Preserve Stem	Size 8
PRPR0009	Profemur® Preserve Stem	Size 9
PRPR0010	Profemur® Preserve Stem	Size 10
PRPR0011	Profemur® Preserve Stem	Size 11
PRPR0012	Profemur® Preserve Stem	Size 12

Profemur® Plus Modular Necks

COCRKITB

Catalog No.	Description
PHAC1202	Straight Short CoCr
PHAC1204	Straight Long CoCr
PHAC1212	Ante/Retro - Varus/Valgus 2 Short CoCr
PHAC1214	Ante/Retro - Varus/Valgus 2 Long CoCr
PHAC1222	Ante/Retro - Varus/Valgus 1 Short CoCr
PHAC1224	Ante/Retro - Varus/Valgus 1 Long CoCr
PHAC1232	Ante/Retro 8° Short CoCr
PHAC1234	Ante/Retro 8° Long CoCr
PHAC1242	Ante/Retro 15° Short CoCr
PHAC1244	Ante/Retro15° Long CoCr
PHAC1252	Varus/Valgus 8° Short CoCr





NOTE: The Broach handle and Tommy Bar are shown in the photo for the Profemur® Preserve instrument kit, but are not included in PPREKIT1 and must be ordered as SKUs, if needed. The Tommy Bar is also available in PRGIKIT1.

Profemur® Preserve Instruments

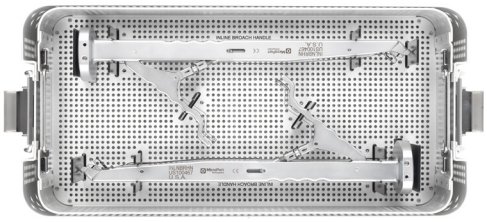
PPREKIT1

Catalog No.	Description
20070185	Lateralizing Rasp
20070186	Profemur® Preserve Canal Finder
PPF60200	Final Stem Impactor
PPREBR01	Profemur® Preserve Broach Size 1
PPREBR02	Profemur® Preserve Broach Size 2
PPREBR03	Profemur® Preserve Broach Size 3
PRMOD451	Profemur® Modular Pocket Stem Inserter
PRPRBR04	Profemur® Preserve Broach Size 4
PRPRBR05	Profemur® Preserve Broach Size 5
PRPRBR06	Profemur® Preserve Broach Size 6
PRPRBR07	Profemur® Preserve Broach Size 7
PRPRBR08	Profemur® Preserve Broach Size 8
PRPRBR09	Profemur® Preserve Broach Size 9
PRPRBR10	Profemur® Preserve Broach Size 10
PRPRBR11	Profemur® Preserve Broach Size 11
PRPRBR12	Profemur® Preserve Broach Size 12
PRPRPB01	Profemur® Preserve Piloted Modular Broach Size 1
PRPRSTBR	Profemur® Preserve Starter Broach

Profemur® Preserve X-Ray Template

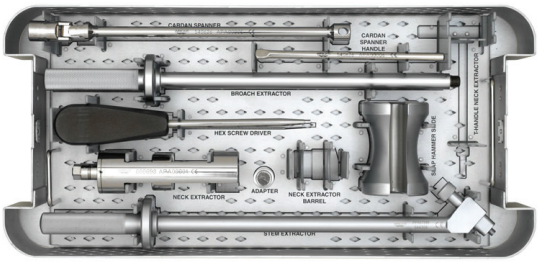
Catalog No.	Description
PPREXR15	Profemur® Preserve Modular X-Ray Templates 15% Magnification
PPRCXR15	Profemur® Preserve Classic X-Ray Templates 15% Magnification

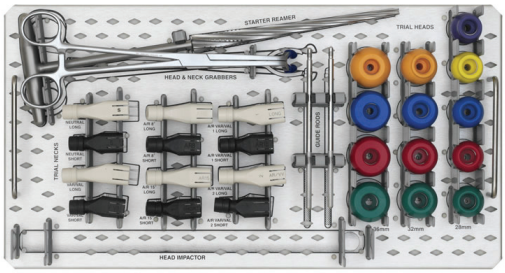
Inline Broach Handle Kit

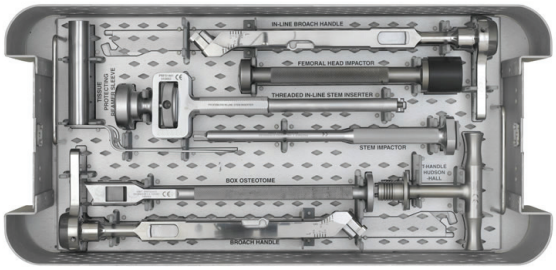


SPBHKIT1

Catalog No.	Description	Quantity
INLNBRHN	Inline Broach Handle	2







Profemur® Standard Instrument Kit

PRGIKIT1

Catalog No.	Description
20070050	Modular Neck Inserter
4400FI0000	Femoral Head Impactor
APA00001	Head/Neck Extractor
APA00003	Head/Neck Extractor Adaptor 12/14
APA00005	Head/Neck Extractor Cardan Spanner Hex
APA00006	Head/Neck Extractor Tommy Bar
APA02121	Femoral Trial Head 28mm Short (-3.5mm)
APA02122	Femoral Trial Head 28mm Medium (+0mm)
APA02123	Femoral Trial Head 28mm Long (+3.5mm)
APA02124	Femoral Trial Head 28mm XLong (+7mm)
APA02125	Femoral Trial Head 28mm XXLong (+10.5mm)
APA02142	Femoral Trial Head 36mm Short (-3.5mm)
APA02144	Femoral Trial Head 36mm Medium (+0mm)
APA02146	Femoral Trial Head 36mm Long (+3.5mm)
APA02148	Femoral Trial Head 36mm XLong (+7mm)
APA02151	Femoral Trial Head 32mm Short (-3.5mm)
APA02152	Femoral Trial Head 32mm Medium (+0mm)
APA02153	Femoral Trial Head 32mm Long (+3.5mm)
APA02154	Femoral Trial Head 32mm XLong (+7mm)
APA04241	Profemur® MIS Broach Handle (Qty 2)
APA04244	Broach Handle Alignment Guide Rod (Qty 2)
APA04750	Profemur® Starter Reamer
APA11102	Profemur® Short Straight Plastic Trial Neck
APA11104	Profemur® Long Straight Plastic Trial Neck
APA11112	Profemur® Short A/R Var/Val 1 Plastic Trial Neck
APA11114	Profemur® Long A/R Var/Val 1 Plastic Trial Neck
APA11122	Profemur® Short A/R Var/Val 2 Plastic Trial Neck
APA11124	Profemur® Long A/R Var/Val 2 Plastic Trial Neck
APA11132	Profemur® Short A/R 8° Plastic Trial Neck
APA11134	Profemur® Long A/R 8° Plastic Trial Neck
APA11142	Profemur® Short A/R 15° Plastic Trial Neck
APA11144	Profemur® Long A/R 15° Plastic Trial Neck
APA11152	Profemur® Short Var/Val 8° Plastic Trial Neck
APA11154	Profemur® Long Var/Val 8° Plastic Trial Neck
K0001016	Quick Disconnect T-Handle
PP275400	Hex Screwdriver
PPR67688	Slap Hammer Stem Extractor
PRFS0450	Profemur® Box Chisel
PRFS0460	Profemur® Screwdriver Inserter
PRFS0462	Profemur® Broach Extraction Shaft
PRFS0463	Profemur® Tissue Protecting Sleeve
PRFS1461	Profemur® Threaded In-Line Stem Inserter

Chapter 8

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 titanium plasma spray coatings applied to implant surfaces are intended for uncemented 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.

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 (Femoral Head and Stems, Modular Necks and Proximal Body)

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. Prior to assembly, surgical debris must be cleaned from the interior of the female seat of the proximal body 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.

Compatible Modular Femoral Heads

Stems and modular necks with the MicroPort 12/14 SLT Taper should only be used in combination with femoral heads with the MicroPort 12/14 SLT Taper. Cobalt chrome femoral heads with the MicroPort 12/14 SLT Taper are designed for use with cobalt-chromium-molybdenum, titanium alloy and ISO 5832-9 stainless steel (not available in the U.S. or Canada) femoral components with the MicroPort 12/14 SLT Taper.

The neck/body component or neck/femoral stem should be changed only when clinically necessary. Refer to proper neck extraction technique in the surgical technique.

Modular Necks

- Cobalt Chrome Modular Necks are not for use with the following devices:
  - Alumina (Biolox Forte) "Ceramic Femoral Head" (size 28mm Long)
- In the United States, ONLY the following stems are cleared to be used with both options of titanium or cobalt chrome modular necks:
  - Profemur® R Stem
  - Profemur® Z Grit Blast Stem
  - Profemur® Renaissance® Stem
  - Profemur® LX Revision Stem
  - Profemur® TL Stem

  All other stems are cleared for use with cobalt chrome modular necks only.

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.

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.