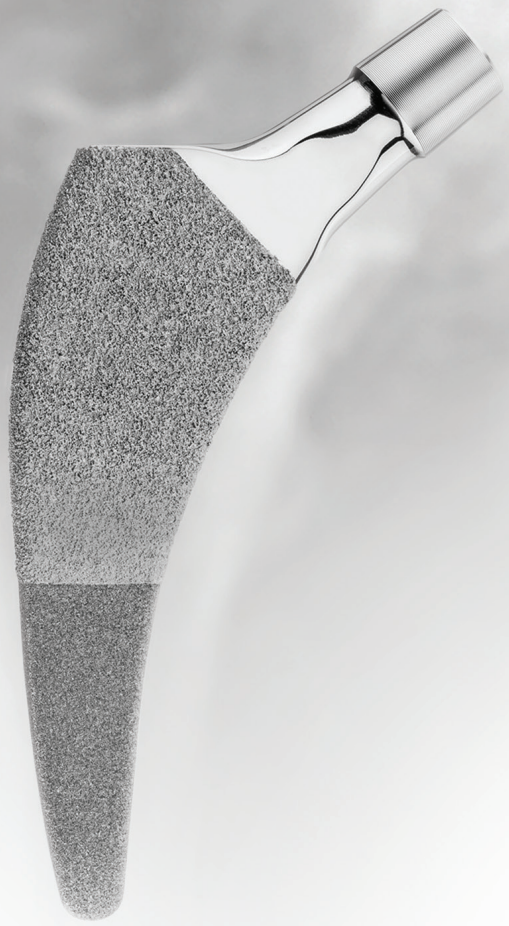
Profemur® Preserve

Total Hip System: Classic and Modular Stems

SURGICAL TECHNIQUE



MicroPort Orthopedics

Integrity In Motion™

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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.

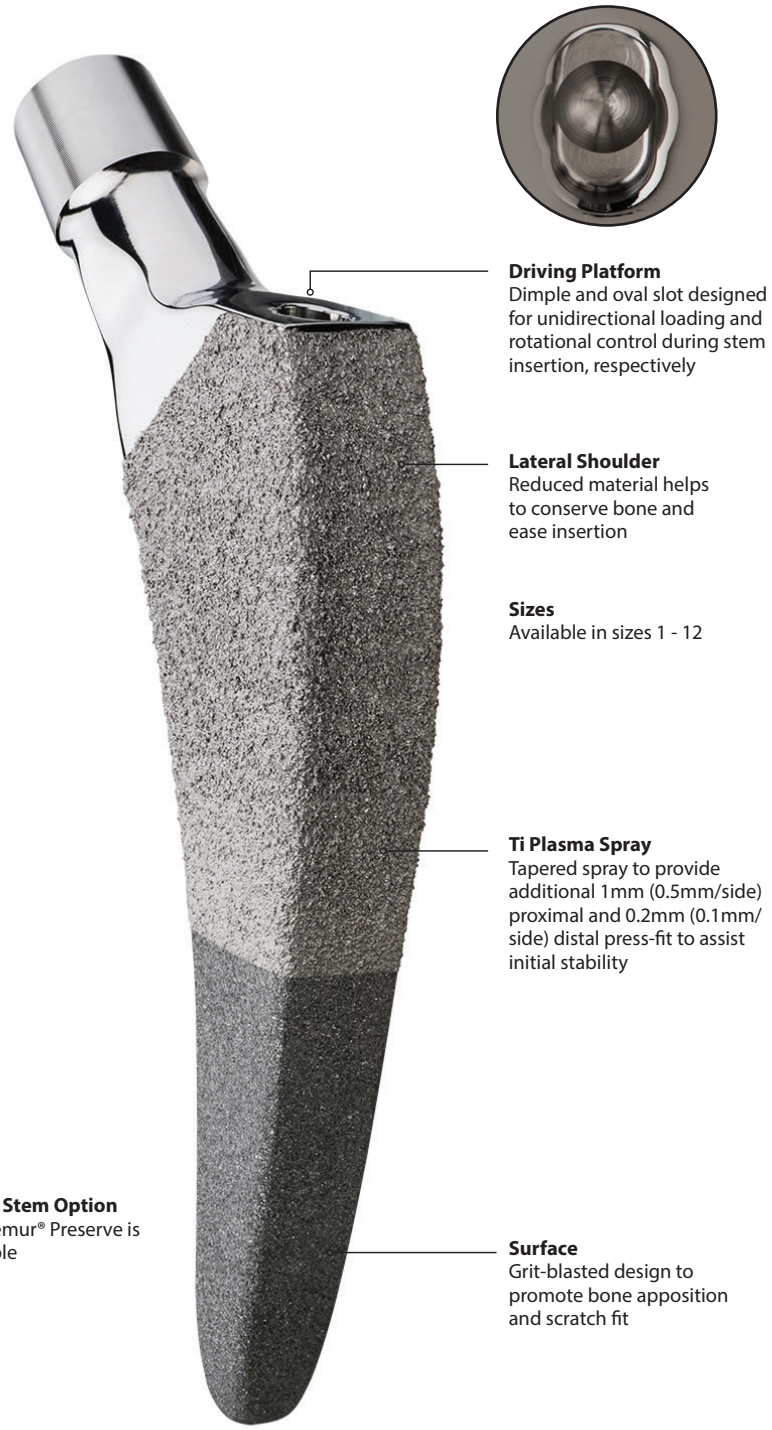
Chapter 1

Product Information

Profemur® Preserve Design Features

Ordering Information		
Templates	PPREXR15 PPRCXR15	Sizes 1-12 (Modular) Sizes 1-12 (Classic)
Surgical Technique	010984	
Instrument Kits	PPREKIT1 (Core) PPREKIT2 (Classic add-on kit) PRGIKIT1 (General)	
Implants	PPREKITA (Stems modular) PPREKITB (Stems classic) COCRKITB (Modular necks)	

Please consult the Instructions for Use package insert for additional risk information.



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

Sizes
Available in sizes 1 - 12

Ti 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
Grit-blasted design to promote bone apposition and scratch fit

A Modular Stem Option
of the Profemur® Preserve is also available

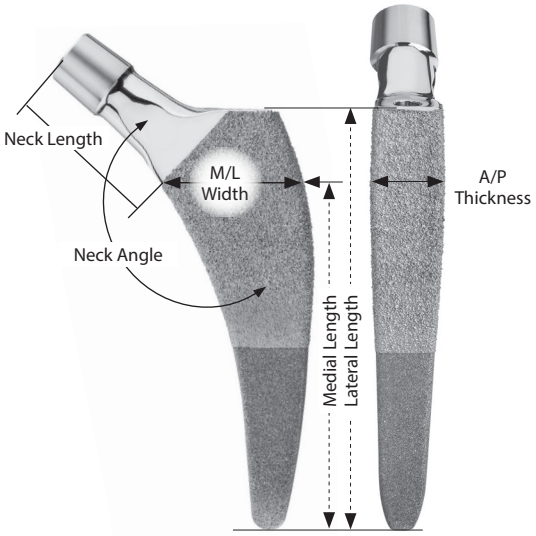
Profemur® Preserve Stems - General Specifications

- Titanium material
- M/L Length: 75 - 99mm
- M/L Width: 28.7 – 38.2mm
- A/P Thickness: 13 – 14.6mm
- Classic Straight neck angle is 135˚
- Classic Varus 8˚neck angle is 127˚

Profemur® Preserve Hip Stems Dimensional Chart

(Measurements in millimeters)

Size	Modular Short Neck			Modular Long Neck			Classic Neck			Stem Measurements			
	Neck Length	Leg Length	Offset	Neck Length	Leg Length	Offset	Neck Length	Leg Length	Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
Straight (135˚)													
1	25	26	33	35	33	41	27	27	35	75	28.7	13	91.5
2	25	26	34	35	33	42	27	27	36	75	29.5	13.2	91.5
3	25	26	34	35	33	44	27	27	36	75	30.1	13.3	91.5
4	25	26	35	35	33	45	27	27	37	75	30.9	13.4	91.5
5	25	26	36	35	33	45	30	29	40	78	31.7	13.6	94.5
6	25	26	36	35	33	47	30	29	41	81	32.5	13.7	97.5
7	25	26	37	35	33	47	30	29	41	84	33.3	13.9	100.5
8	25	26	37	35	33	41	30	29	42	87	34.2	14	103.5
9	25	26	38	35	33	42	34	32	45	90	35.2	14.2	106.5
10	25	26	39	35	33	44	34	32	46	93	36.2	14.3	109.5
11	25	26	39	35	33	45	34	32	47	96	37.2	14.6	112.5
12	25	26	40	35	33	45	34	32	47	99	38.2	14.6	115.5
Varus 8˚ (127˚)													
1	26	24	36	36	30	45	29	24	41	75	28.7	13	91.5
2	26	24	37	36	30	46	29	24	41	75	29.5	13.2	91.5
3	26	24	37	36	30	48	29	24	42	75	30.1	13.3	91.5
4	26	24	38	36	30	49	29	24	42	75	30.9	13.4	91.5
5	26	24	39	36	30	49	33	27	46	78	31.7	13.6	94.5
6	26	24	39	36	30	51	33	27	46	81	32.5	13.7	97.5
7	26	24	40	36	30	51	33	27	47	84	33.3	13.9	100.5
8	26	24	40	36	30	45	33	27	47	87	34.2	14	103.5
9	26	24	41	36	30	46	37	29	51	90	35.2	14.2	106.5
10	26	24	42	36	30	48	37	29	51	93	36.2	14.3	109.5
11	26	24	42	36	30	49	37	29	52	96	37.2	14.6	112.5
12	26	24	43	36	30	49	37	29	53	99	38.2	14.6	115.5



Offset is based on a +0 size head.
Measurements are stem's substrate.

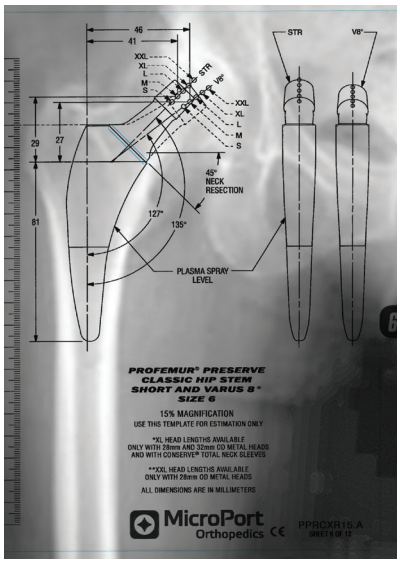
Head Center Adjustment Chart

(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 2

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, 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 AP 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.

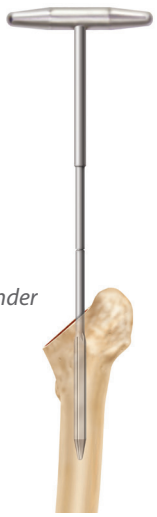
Both the A/P and lateral views are needed to illustrate the impact of choosing an AR/VV neck because the combination necks provide multi-dimensional positioning. Each AR/VV neck provides 4° anteversion/retroversion and 6° varus/valgus. The impact of each AR/VV option (1 or 2) depends upon which hip is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

Chapter 3

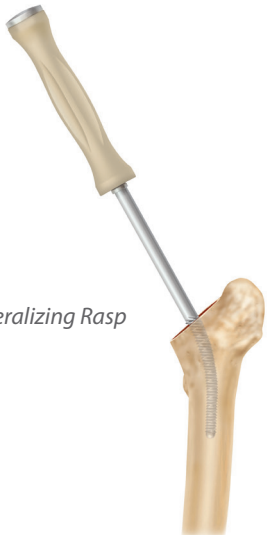
Surgical Technique

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 45º 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

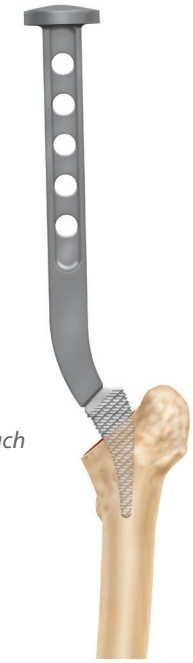
Prepare the metaphyseal region of the femoral canal with the Lateralizing Rasp (P/N 20070185). The shaft of this instrument has aggressive teeth and is curved with a radius between those of the medial and lateral surfaces of the Profemur® Preserve implants.

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 at the level of the neck resection.

Femoral Broaching

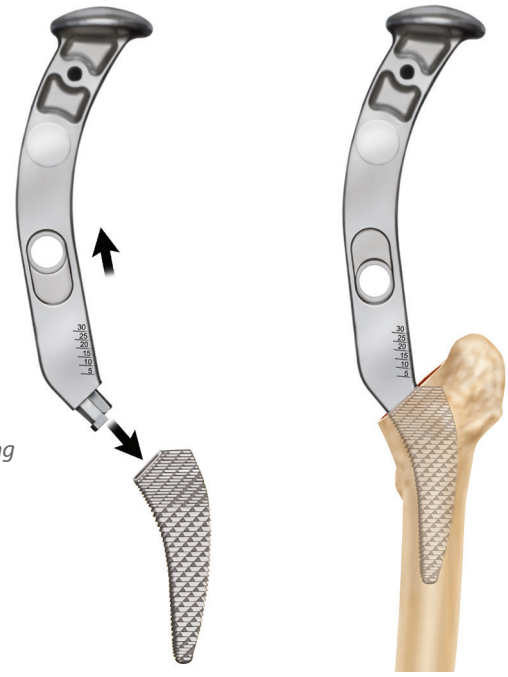
Attach the broach handle of choice (P/N PPW38078 is shown) to the appropriate size Profemur® Preserve broach (P/Ns PPREBR01 - PPREBR03 and PRPRBR04 - PRPRBR12). The broaches are designed to engage any Profemur® style broach handle. Starting with the modular broach that is one size larger than the starter or piloted modular broach, begin broaching using a mallet with short, controlled strokes. A Tommy Bar is available for increased leverage (P/N APA00006).

Tommy Bar
P/N APA0006

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.

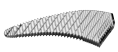
Continue broaching until an optimal fit is found. This will be denoted by a change in tone or resistance as the rounded corners of the broach contact the cortical bone of the femur. To verify a secure fit, the broach handle can be rotated relative to the femur. With proper cortical contact, the broach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

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.

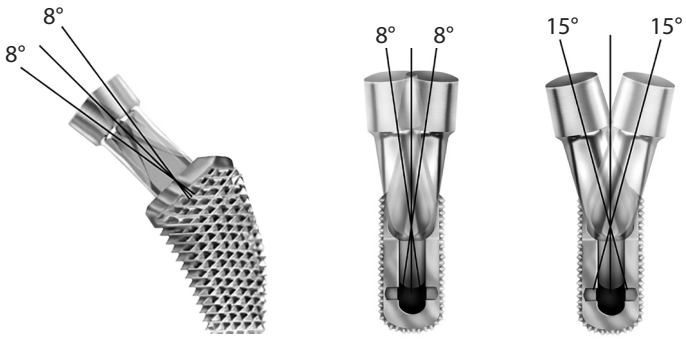
2. If a broach smaller than the size templated becomes tight, hard bone at the lateral femoral neck may be pushing the broach into varus. Use the lateral edge of the broach to restore a neutral position. Additional broaching may be necessary.

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 - APA11154 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.

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® Preserve Classic, six dedicated trial necks have to be used (PPRTNG1S, PPRTNG1E, PPRTNG2S, PPRTNG2E, PPRTNG3S and PPRTNG3E). Those specific trial necks are included in the PPREKIT2.

Brief Summary of Modular Neck Options

- 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˚.

Femoral Trial Head
P/N APA02144

- 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.

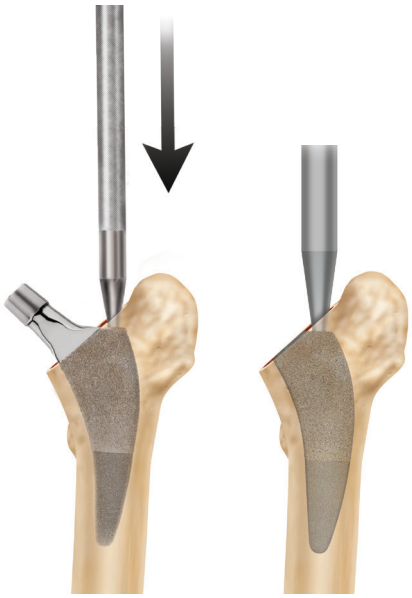
- When broach sizes 1 to 4 are implanted, necks PRTNG1S and PPRTNG1E can be selected to replicate a neutral neck axis (135°) or a varus neck axis (127°).
- When broach sizes 5 to 8 are implanted, necks PRTNG2S and PPRTNG2E can be selected to replicate a neutral neck axis (135°) or a varus neck axis (127°).
- 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°).

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

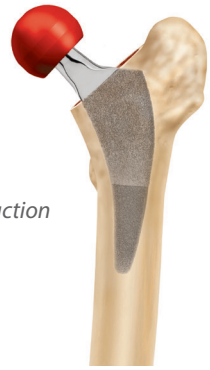
Profemur® Preserve Classic Trial Necks Sizes 5-8 P/N PPRTNG2S and PPRTNG2E

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 by hand and seat it as far as possible. 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.

Modular Stem Insertion (Optional)

Alternatively, 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.

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 necks and trial heads 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® Modular Pocket Stem Inserter
P/N PRMOD451

Implant Assembly

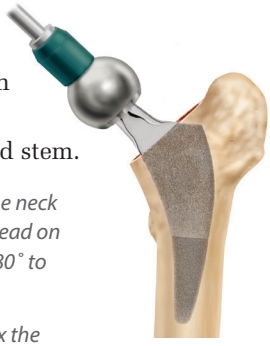
To properly assemble and impact a Profemur® modular neck, the following procedure is recommended:

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. 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.

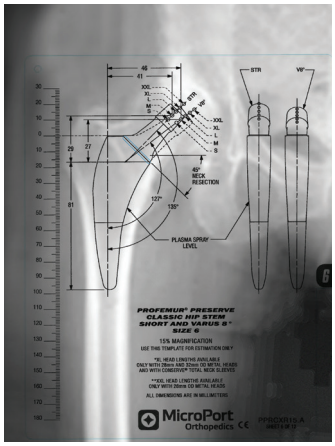


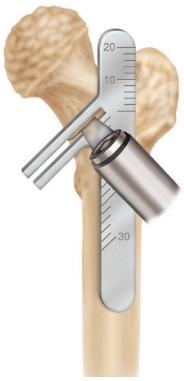
NOTE: If using a ceramic head, securely fix the neck into the stem by impaction, then place the head on the neck by hand, push and turn the head 180˚ to securely lock it in place.

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

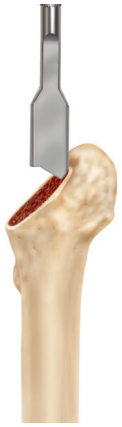
Chapter 4

Technique Overview



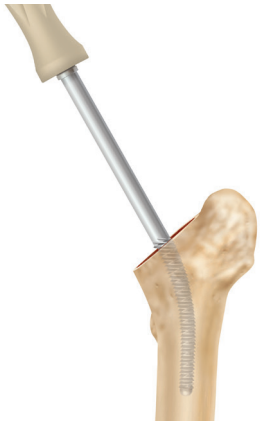


1. Femoral Neck Osteotomy

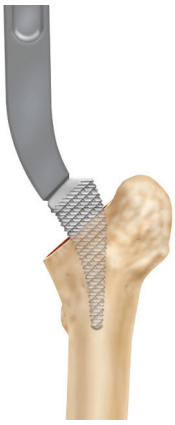


2. Open the Femoral Canal

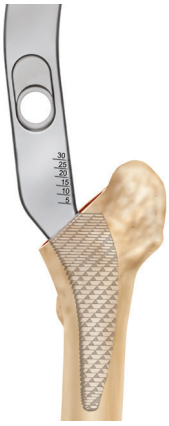
3. Canal Finder
(optional)



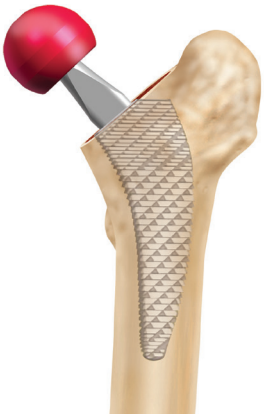
4. Lateralizing Rasp



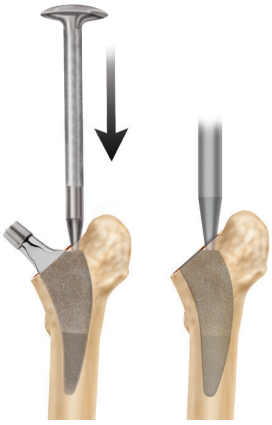
5. Starter Broach and Piloted Modular Broach



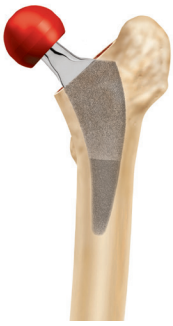
6. Femoral Broaching



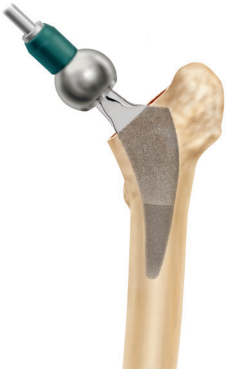
7. Trial Reduction



8. Stem Insertion



9. Final Trial Reduction

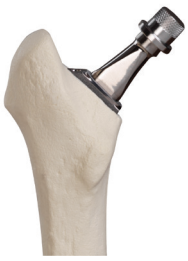


10. Implant Assembly

Femoral Stem Removal - Modular Option

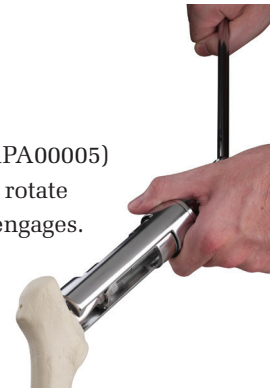
STEP ONE: Modular Neck Removal

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

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.

STEP TWO: Stem R emoval

The thread at the base of the 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.

12/14 Adapter
P/N APA00003

Head/Neck Extractor
P/N APA00001

Spanner Handle
P/N APA00005

Tommy Bar
P/N APA00006

Hex Screwdriver
P/N PP275400

Femoral Stem Extractor
P/N PPR67688

Femoral Stem Removal - Classic Option

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.

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.

Perfecta® Universal Stem Extractor
P/N 4700SE05

Slap Hammer
P/N 4700SH0000

Chapter 5

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°
PPRECAD1	Classic Trial Necks Caddy

Profemur® Preserve Stems

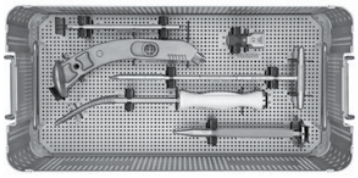
PPREKITA

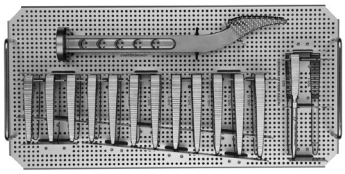
Catalog No.	Description	Size
PPRE0001	Profemur® Preserve Stem	Size 1
PPRE0002	Profemur® Preserve Stem	Size 2
PPRE0003	Profemur® Preserve Stem	Size 3
PRPR0004	Profemur® Preserve Stem	Size 4
PRPR0005	Profemur® Preserve Stem	Size 5
PRPR0006	Profemur® Preserve Stem	Size 6
PRPR0007	Profemur® Preserve Stem	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
PHAC1204	Straight Long
PHAC1212	Ante/Retro - Varus/Valgus 2 Short
PHAC1214	Ante/Retro - Varus/Valgus 2 Long
PHAC1222	Ante/Retro - Varus/Valgus 1 Short
PHAC1224	Ante/Retro - Varus/Valgus 1 Long
PHAC1232	Ante/Retro 8° Short
PHAC1234	Ante/Retro 8° Long
PHAC1242	Ante/Retro 15° Short
PHAC1244	Ante/Retro15° Long
PHAC1252	Varus/Valgus 8° Short
PHAC1254	Varus/Valgus 8° Long





* 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.

Instruments

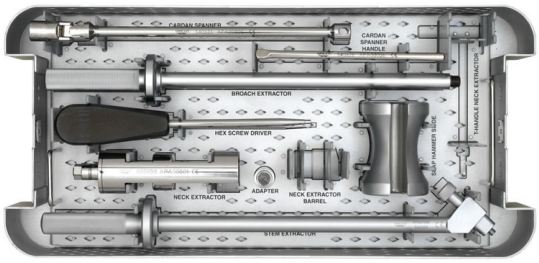
Profemur® Preserve Instruments

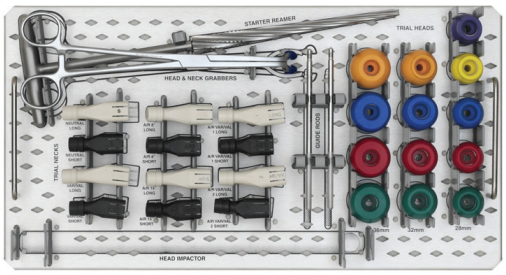
PPREKIT1

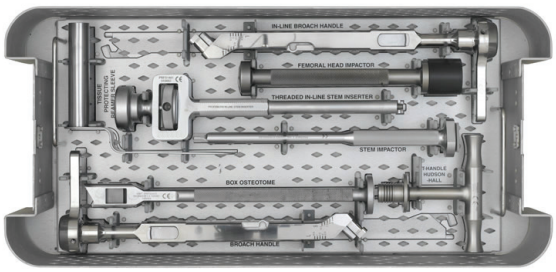
Catalog No.	Description
PPREBR01	Profemur® Preserve Broach Size 1
PPREBR02	Profemur® Preserve Broach Size 2
PPREBR03	Profemur® Preserve Broach Size 3
PRPRBR04	Profemur® Preserve Broach Size 4
PRPRBR05	Profemur® Preserve Broach Size 5
PRPRBR06	Profemur® Preserve Broach Size 6
PRPRBR07	Profemur® Preserve 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
20070186	Profemur® Preserve Canal Finder
20070185	Lateralizing Rasp Long Round
PRPRPB01	Profemur® Preserve Piloted Modular Broach Size 1
PRPRSTBR	Profemur® Preserve Starter Broach
PRMOD451	Profemur® Modular Pocket Stem Inserter
PPF60200	Final Stem Impactor
PPW38078*	Broach Handle
APA00006*	Broach Handle Tommy Bar

X-Ray Templates

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







Profemur® General Instruments

PRGIKIT1

Profemur® Standard Instrument Kit

Catalog No.	Description
APA02121	Femoral Head Trial 28mm Short -3.5mm
APA02122	Femoral Head Trial 28mm Medium +0
APA02123	Femoral Head Trial 28mm Long +3.5mm
APA02124	Femoral Head Trial 28mm Extra Long +7mm
APA02125	Femoral Head Trial 28mm XX-Long +10.5mm
APA02142	Femoral Head Trial 36mm S (-3.5)
APA02144	Femoral Head Trial 36mm M (0)
APA02146	Femoral Head Trial 36mm L (+3.5)
APA02148	Femoral Head Trial 36mm XL (+7)
APA02151	Femoral Head Trial 32mm Short -3.5mm
APA02152	Femoral Head Trial 32mm Medium +0mm
APA02153	Femoral Head Trial 32mm Long +3.5mm
APA02154	Femoral Head Trial 32mm X-Long +7mm
APA00001	Head/Neck Extractor
APA00005	Cardan Spanner Hex.14
APA00006	Tommy Bar for Cardan Spanner
APA00003	Adaptor 12/14
PPR67688	Extractor For ANCA-FIT™ Stem
PRFS0462	Profemur® Broach Extraction
PP275400	Hex Screwdriver
PRFS0450	Profemur® S & Tapered Stem
4400FI0000	Femoral Head Impactor
K0001016	Advance® Quick Disconnect
PRFS0451	Profemur® S Tissue Protecting
APA04750	Profemur® E Initial Reamer
APA04244	Straight Broach Handle
APA04241	Profemur® MIS Broach Handle
20070050	Modular Neck Inserter
PRFS1461	Profemur® Threaded In Line
PRFS0460	Profemur® Screwdriver Inserter
APA11102	Profemur® Short Straight Trial Neck Radio Opaque Radel
APA11104	Profemur® Long Straight Trial Neck Radio Opaque Radel
APA11112	Profemur® Short A/R VAR/VAL 1 Trial Neck Radio Opaque Radel
APA11114	Profemur® Long A/R VAR/VAL 1 Trial Neck Radio Opaque Radel
APA11122	Profemur® Short A/R VAR/VAL 2 Trial Neck Radio Opaque Radel
APA11124	Profemur® Long A/R VAR/VAL 2 Trial Neck Radio Opaque Radel
APA11132	Profemur® Short A/R 8DG Trial Neck Radio Opaque Radel
APA11134	Profemur® Long A/R 8DG Trial Neck Radio Opaque Radel
APA11142	Profemur® Short A/R 15DG Trial Neck Radio Opaque Radel
APA11144	Profemur® Long A/R 15DG Trial Neck Radio Opaque Radel
APA11152	Profemur® Short VAR/VAL 8DG Trial Neck Radio Opaque Radel
APA11154	Profemur® Long VAR/VAL 8DG Trial Neck Radio Opaque Radel
PRGITRAY	Profemur® S/T Tray & Lid General Instrument
PREXTRAY	Profemur® S/T Tray & Lid Extraction

Chapter 6

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.

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

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 (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. Do not resterilize femoral prostheses with ceramic femoral heads seated on the stem. Please refer to the content below for specific warnings and precautions regarding ceramic femoral heads.

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:
  - o Alumina (Biolox Forte) “Ceramic Femoral Head” (size 28mm Long)
- Profemur® Preserve Stems are only intended for use with cobalt chrome modular necks.

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.