

Profemur[®] Preserve

Hip System: Classic Stems

Surgical Technique

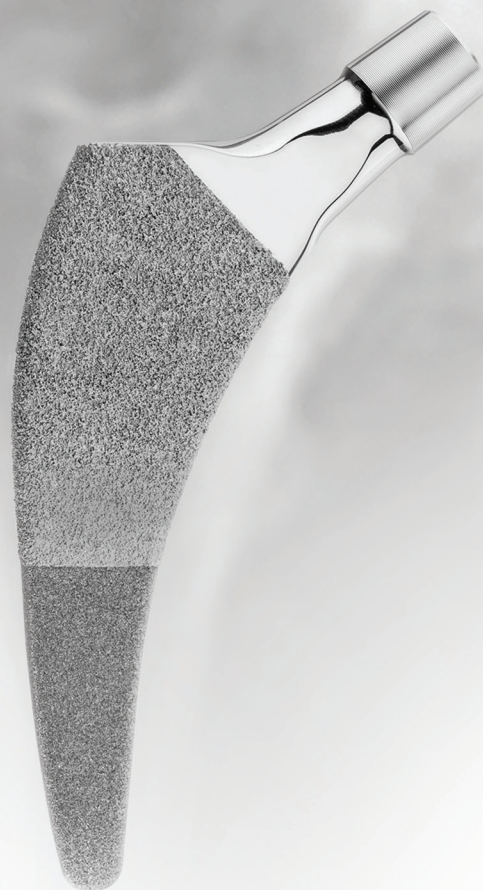


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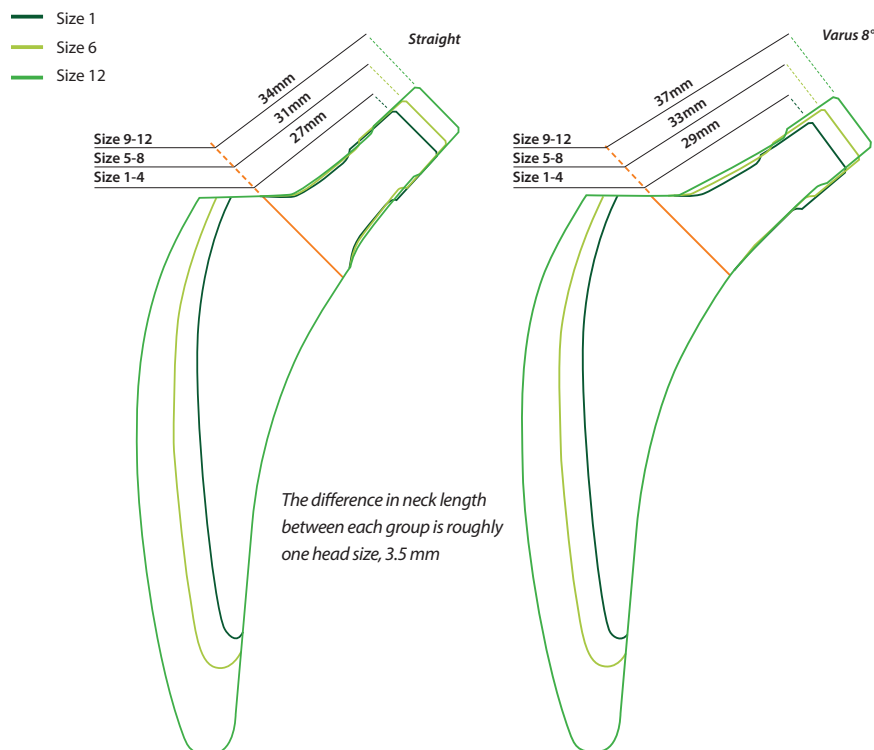
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MicroPort Orthopedics recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness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



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-section³, 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 coverage⁴ while using only three neck lengths at 135° (Straight) and 127° (Varus 8°) CCD angles.

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.

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 012757

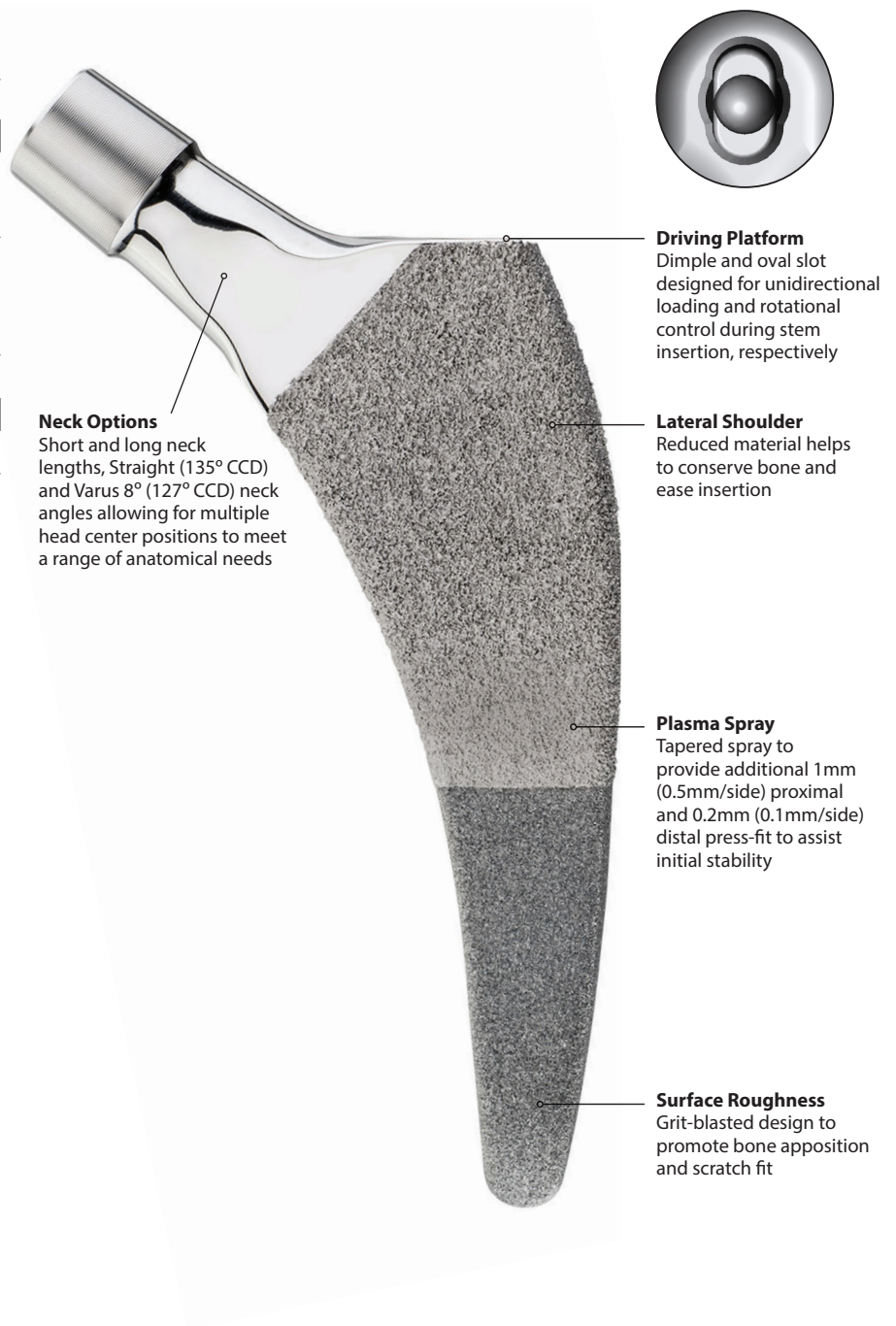
Instrument Kits
PPREKIT1 (Core instruments)
PPREKIT2 (Classic trial necks)
PRCLIMPT (Stem Inserter)
SPBHKIT1 (In-line broach handles)

Implants PPREKITB (Classic stems)

Sizes

Stem 1 - 12

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



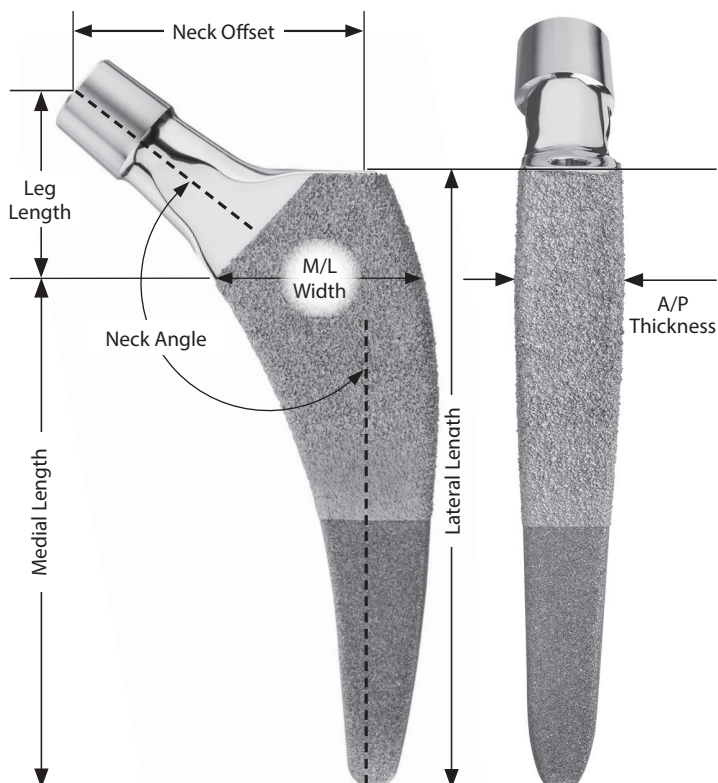
Profemur® Preserve Stems - General Specifications

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

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

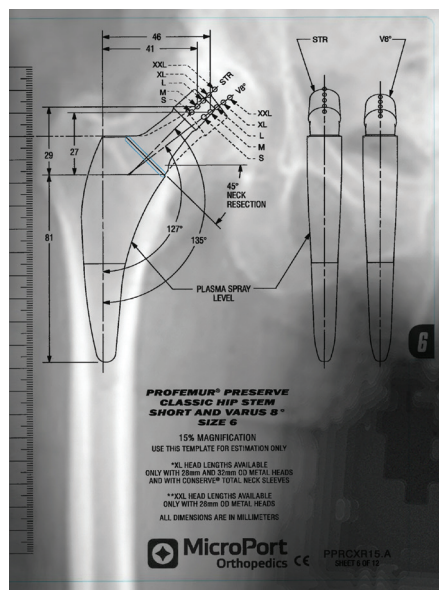


Head Center Adjustment Chart
(Measurements in millimeters)

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

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.

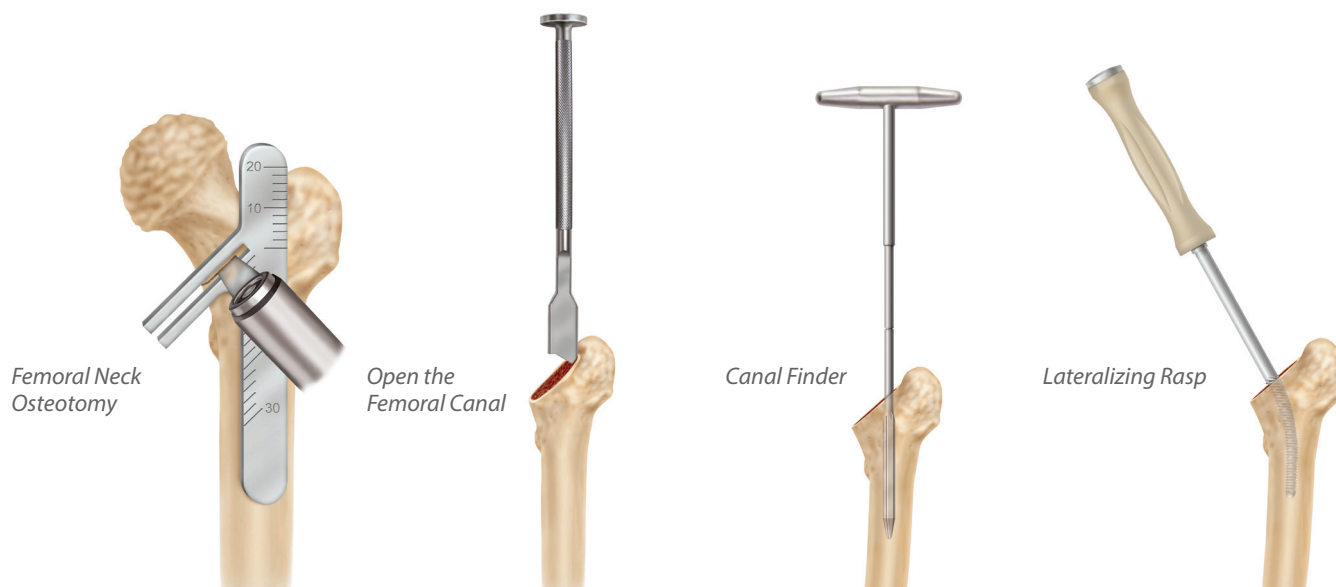
For soft bone, the implant may seat further than the template indicates. An implant larger than the templated size may be required. For strong, healthy bone, an implant smaller than the templated size may be required.

Each circle represents the center of rotation for 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.

Chapter 4

Surgical Technique



Femoral Neck Osteotomy

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

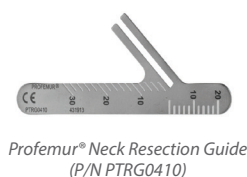
Canal Finder (Optional)

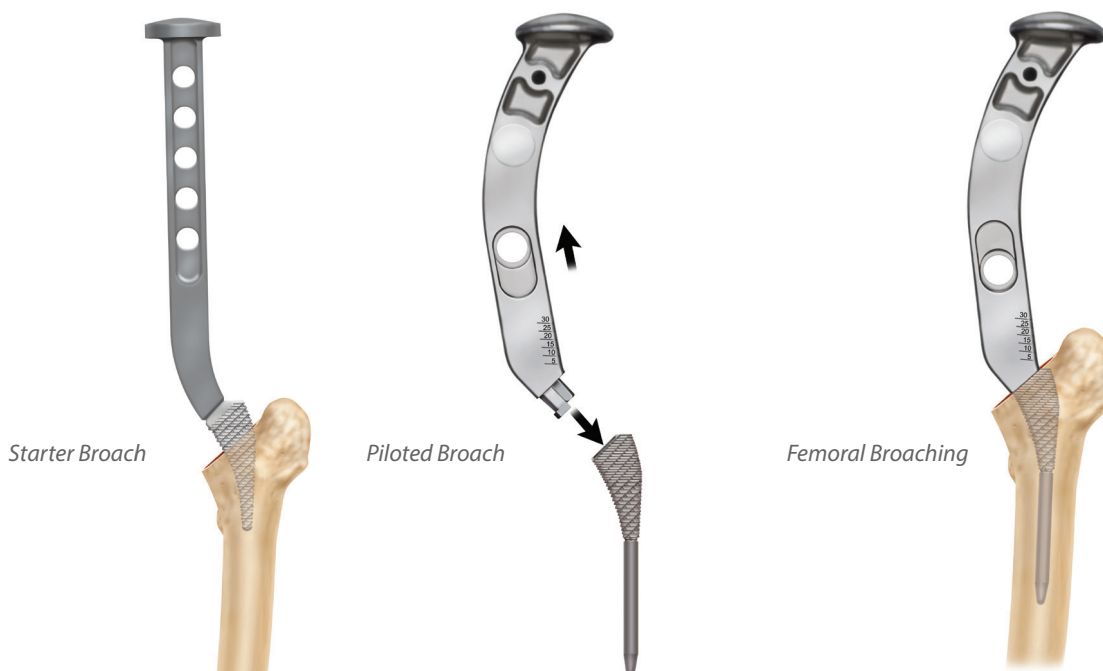
Enter the femoral canal with the Profemur® Preserve Canal Finder (P/N 20070186). A machined groove around the middle of the shaft provides the surgeon with the proper

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.





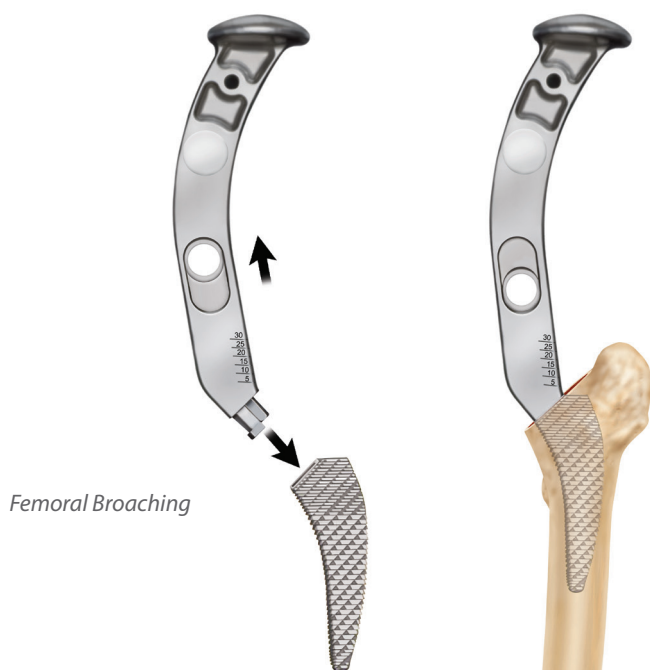
Starter Broach and Piloted Modular Broach

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.





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:

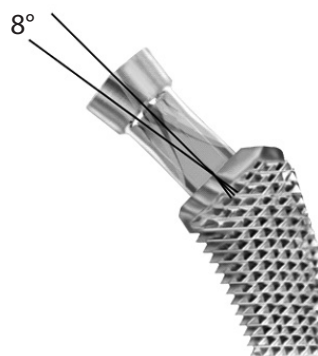
1. The quality of bone plays an integral role in sizing. For soft bone, the broach may seat further than the template indicates. An implant larger than the templated size may be required. Patients with strong, healthy bone might require an implant smaller than the templated size.
2. If a broach smaller 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

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.

Select the appropriate trial neck 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.



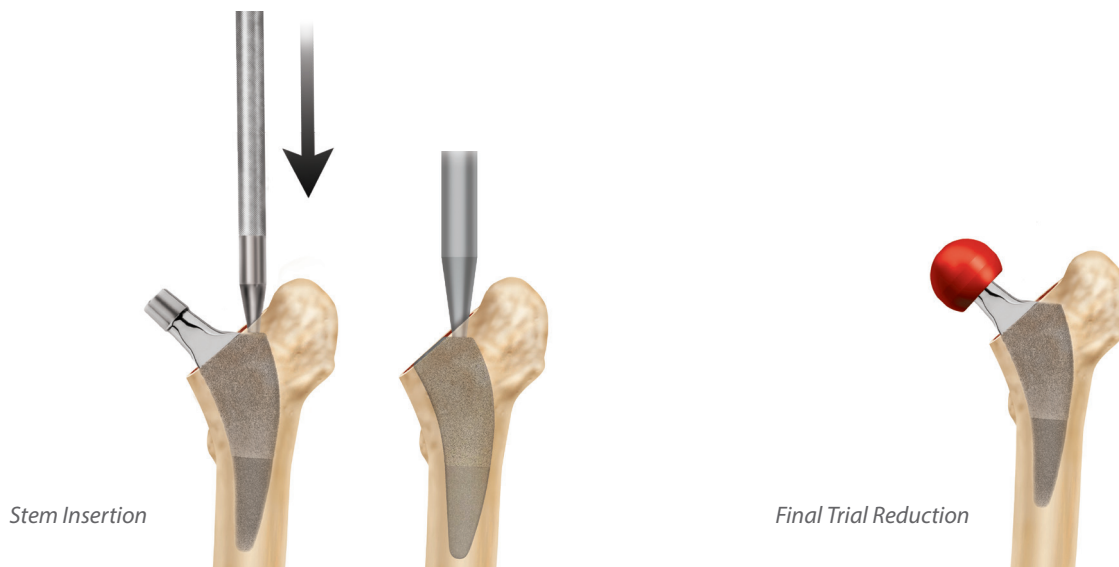
Profemur® Preserve Classic
Trial Necks Sizes 1-4
P/N PPRTNG1S and
PRTNG1E



Profemur® Preserve Classic
Trial Necks Sizes 5-8
P/N PPRTNG2S and
PRTNG2E



Profemur® Preserve Classic
Trial Necks Sizes 9-12
P/N PPRTNG3S and
PRTNG3E



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. 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.

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.



Final Stem Impactor
P/N PPF60200



Profemur® Classic Stem Inserter
P/N PRCLIMPT

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.

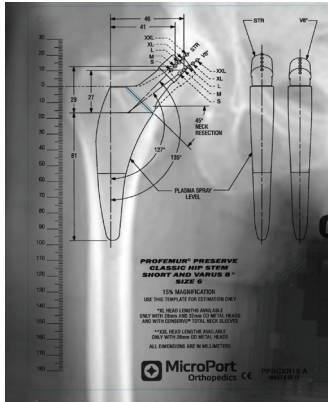
NOTE: Place a femoral head impactor with a plastic impaction tip (such as P/N 4400FI0000 or PPR67702) on ceramic head, and align the impactor with the femoral neck axis of the stem implant. With a moderate tap of the hammer in an axial direction, firmly impact the ceramic head until it is fully seated.

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.

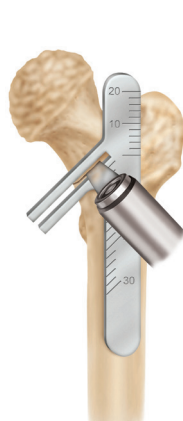


Chapter 5

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

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

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

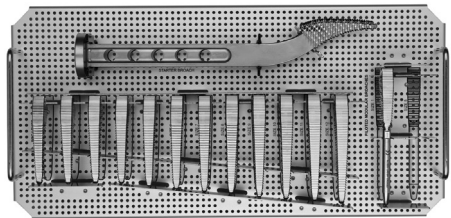
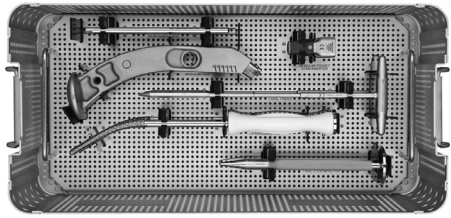


Profemur® Preserve Classic Trial Necks Kit

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°





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	Laterizing 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

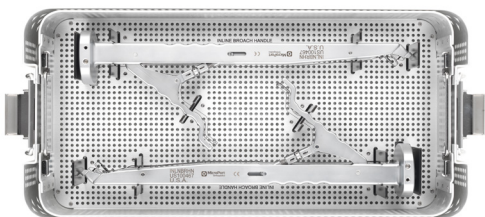
Profemur® Preserve X-Ray Template

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

Inline Broach Handle Kit

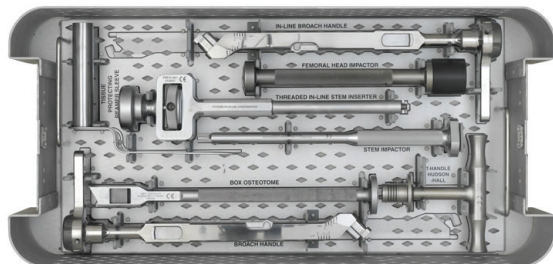
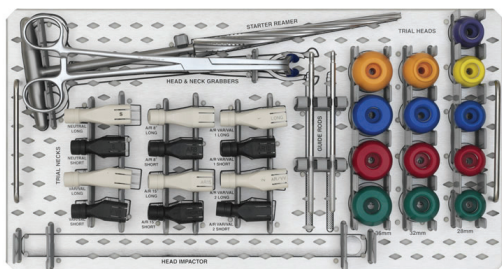
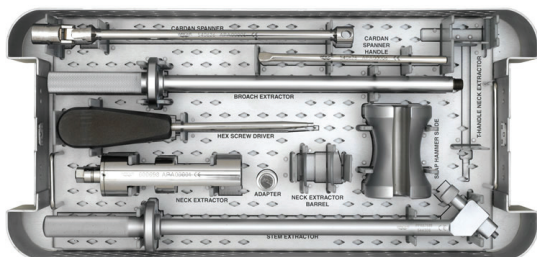
SPBHKIT1

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 Heads, Neck Trunnions)

Scratching of femoral heads and neck trunnions should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Ensure components are firmly seated to prevent disassociation. The femoral head and neck trunnion **must** be clean and dry before assembly.

Compatible Modular Femoral Heads

Stems 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 modular femoral heads should be changed only when clinically necessary.

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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