Profemur® R

Surgical Technique

MicroPort Orthopedics

Full Function, Faster®

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.

TABLE OF CONTENTS

PREFACE DESIGN FEATURES OF THE PROFEMUR® R HIP SYSTEM

CHAPTER 1 PREOPERATIVE PLANNING

CHAPTER 2 SURGICAL TECHNIQUE

CHAPTER 3 IMPLANT REMOVAL

CHAPTER 4 TECHNIQUE OVERVIEW

CHAPTER 5 IMPLANT SPECIFICATIONS

CHAPTER 6 INDICATIONS AND WARNINGS

Preface

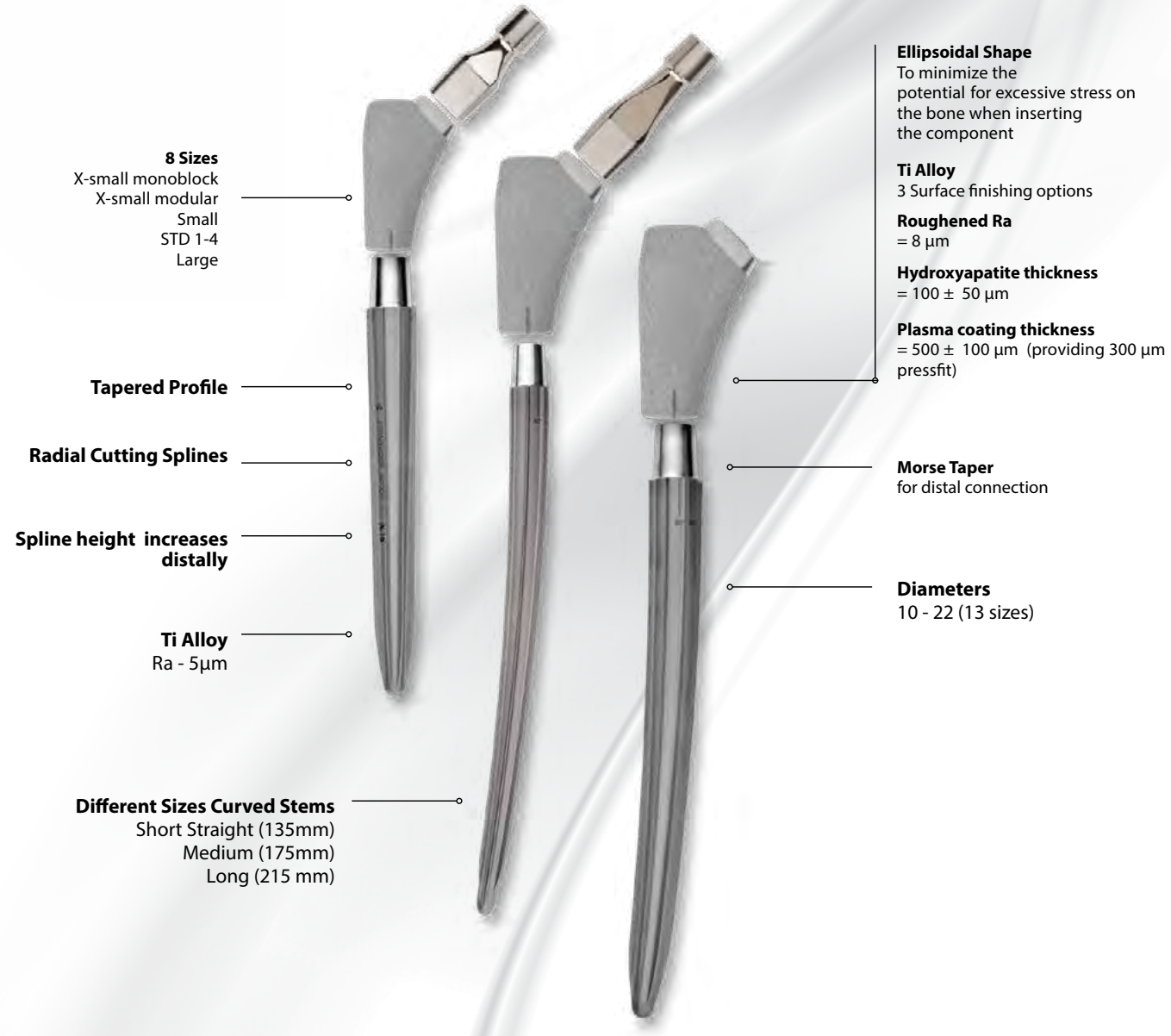
Ordering Information		
Templates	PFM4CL01E	
	PFM4CL02E	
Surgical Technique	011407C	
Instruments	APH00000	General Instruments Set
	APH02111	Profemur® R Instruments
Implants	PRORKITA	Tapered Stems
	PRORKITC	HA prox. bodies
	3251KITB	Plasma prox. bodies
	3251KITC	Grit blasted prox. bodies
	PRORKITB	Adaptors
	COCRKITA	Modular Necks
	SUFIKITA	Metal Heads
	CERAKITA	Ceramic Heads

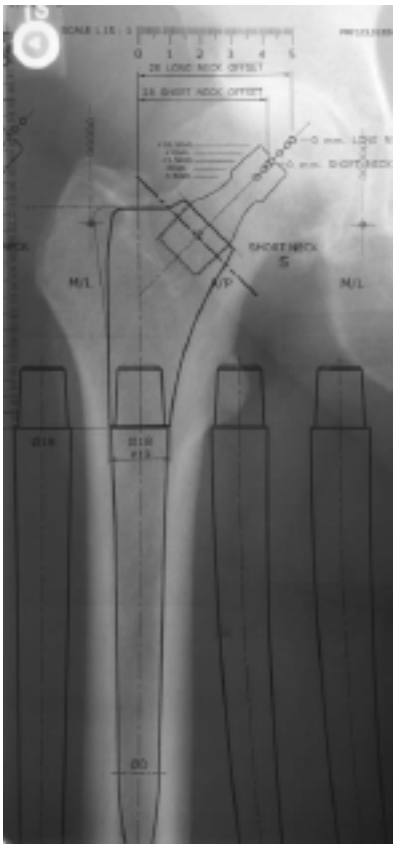
DESIGN FEATURES OF THE PROFEMUR® R REVISION SYSTEM

Access to the hip joint is performed with the preferred surgical approach.

All Components are fully interchangeable.

Potential to obtain the best possible stability and adaptation of the system to the femoral anatomy.





Chapter 1

PRE OPERATIVE PLANNING

Recommended Templating Procedure

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

When positioning the PROFEMUR® R Hip System, it has been found advantageous to seat the implant at a depth that would allow a short neck with a medium head to approximate the height of the center of the femoral head. Seating the implant at this level will allow the most versatility from the modular head and necks during the trialing process. This position is predominantly determined through preoperative X-ray templating.

When templating, appropriate proximal body size is determined first. The proximal body and distal stem templates should be used in conjunction to ensure accurate alignment. This is achieved when cortical contact is obtained on the medial, lateral, anterior and posterior sides of the implant. This will reduce the likelihood of stress shielding. Reference the implant position to a bone landmark to use as a guide for distal and proximal reaming to ensure the final implant will sit at the desired level. The proximal body must be templated both in lateral view and in A/P view.

From this point, the appropriate distal stem is determined by finding the stem size that provides the most ideal canal fit.

The anatomical curved medium and long distal stems can be adjusted to match the natural femoral shaft curvature, whilst the position of the proximal part allows separate consideration of antetorsion.

The choice of modular necks and different head sizes further allows adjustment of leg length and geometry between stem and cup.

PRE OPERATIVE PLANNING

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.

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 templates use circles/squares to compare the impact of choosing a neutral neck and necks with 8° or 15° anteversion/retroversion. Both the A/P and lateral views are needed to illustrate the impact of choosing an AR/VV neck because the combination necks provide multi-dimensional positioning. Each AR/VV neck provides 4° anteversion/retroversion and 6° varus/valgus. The impact of each AR/VV option (1 or 2) depends upon which hip is being considered. Therefore, caution should be used to ensure that the appropriate combination is planned.

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

Chapter 2

SURGICAL TECHNIQUE

Exposure of the artificial joint and primary implant removal

Access to the hip joint is performed with the preferred surgical approach.

Further dissection may be necessary to mobilize the proximal femur. Once sufficient space between the proximal femur and the pelvis has been created, the hip can be dislocated. The initial femoral implant can now be removed and the entrance to the femoral cavity can be exposed.

Any bone cement, fibrous membrane, or excess tissue must be completely removed from the femoral canal.

Canal Preparation

The clean femoral canal may be initially prepared by utilizing the initial canal reamer (PPW36302) **Figure 1**

The initial canal reamer may also be used to evaluate and probe the femoral canal; assessing orientation and curvature of the femoral shaft. Prior to reaming the femoral canal, the medial aspect of the greater trochanter should be cleared of any overhanging bone to facilitate neutral alignment of the femoral reaming and proximal rasp instruments.

The initial canal reamer features 3 marks on its shaft (SHORT; MEDIUM and LONG): they represent the total length of a STD proximal body coupled with a Short, Medium or Long stem, respectively.

Figure 1

Initial Canal Reamer
PPW36302

Distal Broaching

Distal broaches (to the tips of their teeth) are identical in size to the final implants. Customarily, the final stem implanted is one size larger than the last distal broach used to provide 0.5mm per side of spline bone penetration. (Table 1)

For bowed stems, femoral bow orientation may be assessed with 9mm smooth curved trials before broaching. (APA04430-40). **Figure 2**

Thread the distal broach/trial adaptor (PPW38158) to the selected trial stem. Attach the trial adaptor/trial stem assembly to the distal broach handle (PPW38094) and insert it in the femur. The trial stems feature graduated markings (0°, 30° and 60°) to help assess rotation.

RECOMMENDED	
0.5mm Per Side Press-Fit	
Stem Diameter	***Distal Broach***
10mm	-
11mm	Size 10
12mm	Size 11
13mm	Size 12
14mm	Size 13
15mm	Size 14
16mm	Size 15
17mm	Size 16
18mm	Size 17
19mm	Size 18
20mm	Size 19
21mm	Size 20
22mm	Size 21

Table 1

Figure 2

Broach / Trial Adaptor
PPW38158

Distal Broach Handle
PPW38094

Trial Stems
APA04430-40

Figure 3

Figure 4

Distal Broaches
PA04340-4424

Broach / Trial Adaptor
PPW38158

The distal portion of the femur is prepared with the tapered distal broaches (APA04340-4424). In addition to serve as a broach, the distal broaches act as trials and are utilized to maintain alignment, estimate sizing, and evaluate femoral curvature. Thread the distal broach/ trial adaptor (PPW38158) to the broach.
Assemble the adaptor/distal broach to the distal broach handle by aligning the broach locking collet slot with the peg on the distal broach handle. Lift the locking collet upward and insert the distal broach to the distal broach handle. **Figure 3**

Using a mallet with short, controlled strokes, begin broaching. Sequentially, increase the broach size while broaching.

The distal broach handle has three marks **Figure 3** that correspond to the proximal body heights (SM=Small, ST=Standard, L=Large). Insert the distal broach into the femur until the appropriate depth mark is aligned with the tip of the greater trochanter. For the x-small modular plasma sprayed proximal body, the distal broach handle should be sunk to 4mm below the "SM" depth mark.

If the tip of the greater trochanter is not available as a landmark, an alternative such as the lesser trochanter should be used, and the distance between this point and the average center of rotation estimated pre-operatively with the x-ray templates.

Continue broaching untill the distal broach is fully seated. Once fully seated, lift the distal broach handle locking collet upward and disengage the distal broach handle from the distal broach, while the distal broach remains in the femur.

Junction Reamers (optional)

Figure 5

Figure 6

After the distal broach is secured in the femur, junction reamers (APA04302–043010) matching the proximal body sizes (small through large) can be used to further clean and prepare the proximal femoral portion. Select the appropriate size junction reamer, matching the proximal body size and place it over the distal broach trial adaptor. Continue junction reaming until the junction reamer has bottomed out. **Figure 5 & 6**

After this step, care should be taken to verify that the distal broach adaptor (PPW38158) is securely tightened to the distal broach.

Proximal Rasps

Figure 7

The Profemur® R system has 7 proximal rasps (x-small, small, standard 1 through 4, and large) (APA04248-APA04262). Proximal rasping should be sequential in nature starting with the smallest size and gradually increasing until the appropriate size is found.

Attach the proximal rasp handle (APA04240) to the appropriate proximal rasp by lifting the trigger upward and inserting the locking portion into the oval pocket of the rasp. **Figure 7**

NOTE: The ex-small monoblock proximal body does not have a dedicated proximal rasp. This implant is suggested to be used in femoral osteotomy procedures, where proximal bone preparation is not necessary.

Junction Reamers
APA04302-10

Proximal Rasp Handle
APA04240

Proximal Rasp
APA04248-62

Figure 8

Figure 9

The "0" marks on the "S" and "L" scales on the proximal rasp handle approximate the head center of a medium head on a short or long neck, respectively. Proper depth of the proximal rasp is established by inserting the appropriate depth mark 1-3mm below the tip of the greater trochanter.

The depth of the rasp toothed area of the proximal broach should approximate the final location of the roughened surface or plasma sprayed area of the final implant. Only the toothed area of the rasp corresponds to the implant size. **Figure 8**

Place the proximal rasp over the distal broach trial adaptor and utilizing light mallet blows, advance the proximal rasp. **Figure 9**
Attention should be directed toward positioning the rasp into the best bone for optimum fit and fixation.

If proximal fit is not achieved, remove the proximal rasp, repeat with the next size and continue until the optimal rasp is found. The cannulated design allows proper positioning and alignment for the proximal bodies into the best available bone.

Two proximal marks on the distal broach/ trial adaptor can be utilized to ensure proper proximal rasp depth insertion.

Similar to the marks on the distal broach handle, SM, ST and L are marked on the broach/trial adaptor. However, on this instrument, SM and ST are aligned because the small proximal rasp is elongated, which compensates for the difference between SM and ST marks heights.

Figure 10

Figure 11

Figure 12

Figure 13

Figure 14

Trial Reduction

Once rasping of the metaphyseal part is complete, remove the proximal rasp handle. The distal broach trial adaptor piece can now be removed, using the 3.5mm hex screw driver (PP275400, included in the APH00000 kit).

A final check of anteversion can be made and the locking screw (PPW380077) can be inserted and tightened using the 3.5mm hex screw driver (PP275400). **Figure 10 & 11**

The locking screw is provided with a split washer to maintain a tight fit between the proximal rasps and distal broaches. Ensure that the split washer is separated before tightening to assure spring tension. **Figure 12**

At this time, a trial reduction can be performed by using one of the two metal trial necks. Select the appropriate trial head corresponding the acetabular implant.

The metal trial necks are designed in straight short and long options, only for preliminary evaluation (APA01662 or APA01664). **Figure 13 & 14**

WARNING: For the trial reduction, do not use the plastic trial necks with the broaches. Due to the broach design, the Profemur® R metal trial necks have a different length than the plastic trial necks.

The final trial reduction is accomplished with plastic trial necks on final implants.

3.5mm Hex Screwdriver
PP275400

Locking Screw
PPW38077

Profemur® R Metal Trial Necks
APA01662-64

Extraction of the proximal rasp / distal broach assembly

After trial reduction and adequate offset and leg length have been evaluated, remove the femoral head and metal trial neck components. Reinsert the proximal rasp handle (APA04240) and remove the proximal rasp and distal broach components. **Figure 15**

Figure 15

Before extraction of a bowed distal broach, ensure that the locking screw is tightly secured to maintain orientation of the distal broach and proximal rasp.

A series of marks on the distal broach and proximal rasp correspond to similar markings on the matching proximal body and distal stem implants. By replicating the orientation of these marks on the final implants, reproduction of the correct bow orientation is possible. **Figure 16**

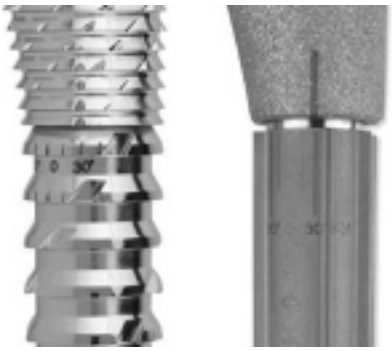


Figure 16

Proximal Rasp Handle
APA04240

Implant Assembly and Insertion

Figure 17

After the appropriate proximal and distal implant components have been selected, they must be connected via the morse taper. If implanting a bowed stem, align the appropriate marks on the proximal body and distal stem, ensuring the tapers of the proximal and distal components are clean.

Place the two components together with hand pressure. Place the distal stem tip on a padded solid surface. Place a swap over the proximal body and apply firm mallet blows to engage the tapers. **Figure 17**

Figure 18

Assemble the stem impactor/extractor (PPW36292) into the proximal hole on the proximal femoral body.
If a x-small monoblock proximal component is used, the x-small impactor/extractor (PPW38166) must be used.
A rotation guide handle (PPW36294) is supplied and can be inserted into the femoral neck taper region of the proximal body if additional rotational control is required during impaction. **Figure 18**

Stem Impactor / Extractor
PPW36292

x-small Impactor / Extractor
PPW38166

Rotation Guide Handle
PPW36294

Implant Assembly and Insertion

Figure 19

After the implant is fully seated in its proper position, remove the impactor handle and insert the proximal distal locking screw to secure the taper between the distal stem and proximal body. **Figure 19**

Further flexibility with regard to the choice of distal stem length may be achieved with the addition of adaptors. No trial components are available for these extensions implants. They are available in two different lengths (26mm and 52mm) and their usage with the selected proximal implant is detailed in Table 2.

P/N	*Use with Prox. Part*	*Length*	*Diameter*
PPW00148	Ex-SMALL Monoblock	26 mm	19
PPW00140	Small / STD1	26 mm	19
PPW00141	STD2	26 mm	21
PPW00142	STD3/STD4/Large	26 mm	23
PPW00144	Small / STD 1-2-3-4 / Large	52 mm	19

Table 2

Figure 20

In case an extension is selected, the standard fixation screw packaged with the proximal body must be replaced with the one packaged with the selected extension adaptor.

Sealing of the proximal component hole is now accomplished by assembling the hole plug to the proximal body. **Figure 20**

ADDENDUM

Adjustment of the proximal body position

If necessary, the proximal body position may be adjusted.

First, replace the impactor/extractor instrument with the proximal-distal separator. (PPW38161 for x-small body or PPW38163, for the other proximal bodies) **Figure 21**

Secondly, insert the threaded separator rod (PPW38159) trough the hole in the impactor/extractor instrument. Attach the distal broach handle (PPW38094) to the separator rod and turn in a clockwise motion until the proximal and distal tapers are slightly separated. **Figure 22**

Remove the separator rod and the impactor/extractor instrument by turning it in a counter-clockwise motion, using the tommy bar (PPB31902) Reposition the proximal body in its proper orientation and continue impaction with the dedicated impactor/extractor instrument (PPW36292 or PPW38166).

After the implant is fully seated in its proper position, remove the impactor/extractor instrument and insert the proximal distal locking screw. Sealing of the proximal component hole is now accomplished by assembling the hole plug to the proximal body.

Figure 21

Figure 22

x-small Proximal - Distal Separator
PPW38161

Proximal - Distal Separator
PPW38163

Tommy Bar
PPB31902

Threaded Separator Rod
PPW38159

Trial Reduction

Perform a final reduction using the trial necks and trial heads to reconfirm stability, range of motion and leg length. Select the appropriate Profemur® trial neck (APA11102- APA11154, included in APH00000) and trial head (APA02121-APA02154, included in APH00000 and APA02112-13) and perform a trial reduction. Once a well-balanced hip has been created with a trial head and trial neck, you can introduce the final neck and head implant. **Figure 23 & 24**

Figure 23

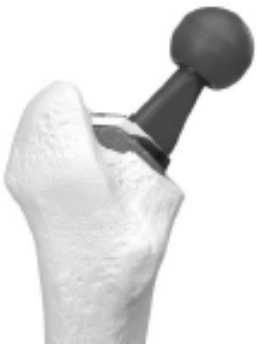


Figure 24

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

In case an x-small monoblock body is used, no trial reduction with modular necks is required.

Brief Summary of Neck Options

- Straight necks create a neutral neck axis (135˚)
- Varus necks decrease the inclination angle to 127˚ (neutral position is 135˚); the femoral head shifts medially and inferiorly; leg length is shortened; offset is increased.
- Valgus necks increase the inclination angle to 143˚; the femoral head shifts laterally and superiorly; leg length is increased; offset is decreased.
- Anteverted necks shift the femoral head anteriorly relative to the stem by 8˚ or 15˚.
- Retroverted necks shift the femoral head posteriorly relative to the stem by 8˚ or 15˚. Retroverted necks prove useful in hips with excess femoral anteversion such as DDH.
- AR/VV necks combine anteversion/retroversion and varus/valgus necks to offer a broad range of multidimensional head positions. Each AR/VV neck provides 4˚ of A/R and 6˚ of V/V.

Step 1

Step 2

Step 3

Step 4

Modular Neck Assembly

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

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

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

Step 3.
Position the leg such that the knee is supported by an assistant on the opposite side of the table. By resting the patient's knee against the mid-section of the assistant, this will provide counter-force against the mallet blows to ensure the impaction load transfer to the neck junction.

Step 4.
Ensure the stem taper is clean and dry prior to assembly, and then affix the femoral head to the neck. Using the head impactor instrument (PPR67702), 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 into place. Place the plastic head impactor on the pole of the ceramic femoral head, and with a moderate tap of the hammer in an axial direction, firmly and definitively fix it on the stem taper.

Figure 25

Figure 26

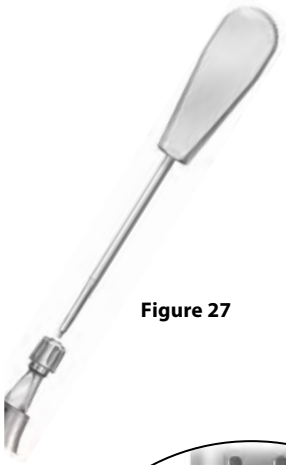


Figure 27

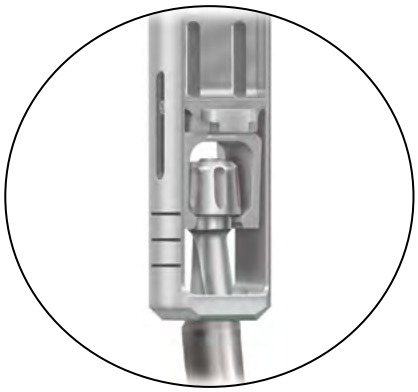


Figure 28

Chapter 3

IMPLANT REMOVAL

Femoral Head and Neck Removal

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Femoral Head Removal

The femoral head is removed by placing a plastic tipped femoral head impactor under the femoral head and applying mallet blows upward until the femoral head is removed. **Figure 25 & 26**

Femoral Neck Extraction

Screw the femoral neck adaptor (APA09501) onto the femoral neck in a clockwise motion. The neck extractor (APA09500) goes over the top of the femoral neck and the adapter is captured by the adjustable hook. By squeezing the handle an extraction force is applied to the neck as the neck extractor pushes against the shoulder of the prosthesis. The extractor will accommodate any style and size of neck in combination with any style and size of prosthesis. **Figure 27 & 28**

Profemur® Modular Necks Extractor Kit

APH04600

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

Figure 29

Figure 30

Removal Proximal Body

Utilizing the screwdriver, remove the proximal body hole plug and loosen the proximal/distal locking screw. Screw the proximal-distal separator (PPW38163 for x-small body or PPW38161, dedicated to the small, standard and large proximal bodies) into the proximal hole on the proximal femoral body . **Figure 29**

Insert the threaded separating rod (PPW38159) through the hole in the impaction handle. Attach the distal broach handle(PPW38094) to the separator rod and turn in a clockwise motion until the proximal and distal tapers are separated. **Figure 30**

Remove the separator rod and cannulated impactor handle by turning it in a counter-clockwise motion, using the tommy bar (PPB31902)

Thread the impactor/extractor (PPW36292 or PPW38166 for x-small monoblock) into the proximal body. Using a mallet or slide hammer, extract the proximal body.

Figure 31

Figure 32

Removal Distal Stem

Thread the distal stem extractor (PPW36300) onto the distal stem. Using the slide hammer (PPW36296), extract the distal stem. **Figure 31 & 32**

x-small Proximal - Distal Separator
PPW38163

Proximal - Distal Separator
PPW38161

Tommy Bar
PPB31902

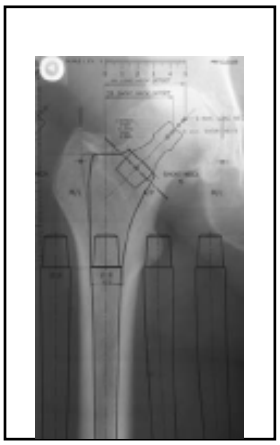
Distal Broach Handle
PPW38094

Distal Stem Extractor
PPW36300

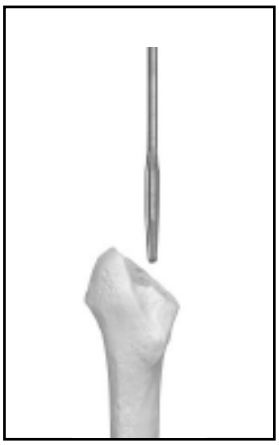
Slide Hammer
PPW36296

Chapter 4

TECHNIQUE OVERVIEW

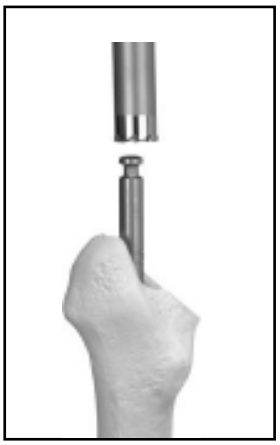


STEP 1 | X-ray templating of lateral and A/P view.



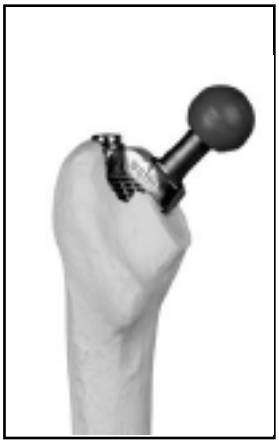
STEP 2 | Find canal axis

STEP 3 | Broach distally until cortical contact is achieved



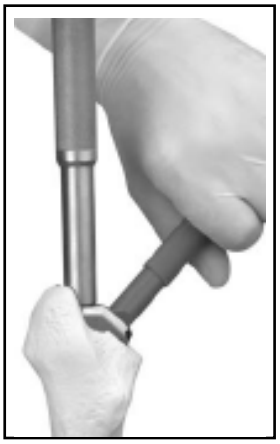
STEP 4 | Proximally ream until appropriate mark is slightly below the greater trochanter.

STEP 5 | Broach up from the smallest size. Broach teeth approximate implant.

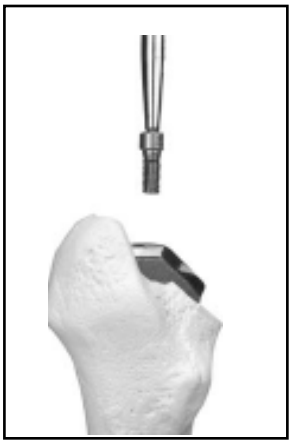


STEP 6 | Trial with metal necks to preliminarily determine neck length.

STEP 7 | Assemble implant on solid surface.



STEP 8 |Insert stem with stem impactor while using the ration guide handle for additional rotation control during impaction



STEP 9 | Insert stem locking screw (must be done before neck insertion).

STEP 10 | Trial using plastic necks and heads.

STEP 11 | Seat neck and head implants.

STEP 12 | Insert hole plug

Chapter 5

IMPLANT SPECIFICATIONS

Proximal Bodies

Proximal bodies Grit Blast

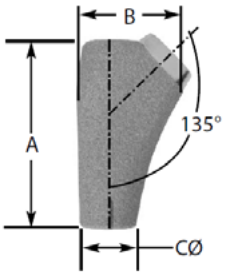


Figure 33

Description	Size	A	B	CØ
Proximal body Sandblasted	EX-Small (monoblock)	54	31	18
Proximal body Sandblasted	Small	54	34	18
Proximal body Sandblasted	Standard 1	67	37	19
Proximal body Sandblasted	Standard 2	67	39	20,5
Proximal body Sandblasted	Standard 3	67	42	22
Proximal body Sandblasted	Standard 4	67	44	23,5
Proximal body Sandblasted	Large	80	47	25

Proximal bodies Plasma Spray

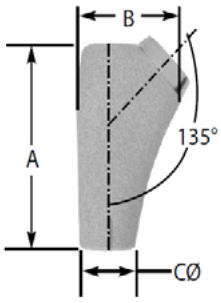


Figure 34

Description	Size	A	B	CØ
Proximal body Ti Plasma Spray	X-Small modular	50	33	18,6
Proximal body Ti Plasma Spray	EX-Small monoblock	54	31,5	18,6
Proximal body Ti Plasma Spray	Small	54	34	18,6
Proximal body Ti Plasma Spray	Standard 1	67	37	19,6
Proximal body Ti Plasma Spray	Standard 2	67	39	21,1
Proximal body Ti Plasma Spray	Standard 3	67	42	22,6
Proximal body Ti Plasma Spray	Standard 4	67	44	24,1
Proximal body Ti Plasma Spray	Large	80	47	25,6

Proximal bodies HA Coated

Description	Size	A	B	CØ
Proximal body HA Coated	EX-Small monoblock	54	31	18
Proximal body HA Coated	Small	54	34	18
Proximal body HA Coated	Standard 1	67	37	19
Proximal body HA Coated	Standard 2	67	39	20,5
Proximal body HA Coated	Standard 3	67	42	22
Proximal body HA Coated	Standard 4	67	44	23,5
Proximal body HA Coated	Large	80	47	25

Stems

Tapered Splined Short (Straight)

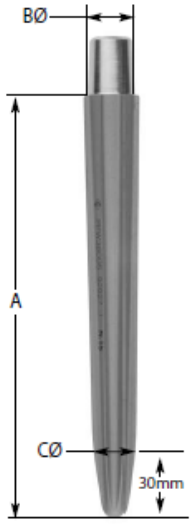


Figure 35

Description	Size	A	BØ	CØ
Tapered Stem Straight	Size 10	135	18	10
Tapered Stem Straight	Size 11	135	18	11
Tapered Stem Straight	Size 12	135	18	12
Tapered Stem Straight	Size 13	135	18	13
Tapered Stem Straight	Size 14	135	18	14
Tapered Stem Straight	Size 15	135	19	15
Tapered Stem Straight	Size 16	135	20	16
Tapered Stem Straight	Size 17	135	21	17
Tapered Stem Straight	Size 18	135	22	18
Tapered Stem Straight	Size 19	135	23	19
Tapered Stem Straight	Size 20	135	24	20
Tapered Stem Straight	Size 21	135	25	21
Tapered Stem Straight	Size 22	135	26	22

Tapered Splined Medium (Bowed)

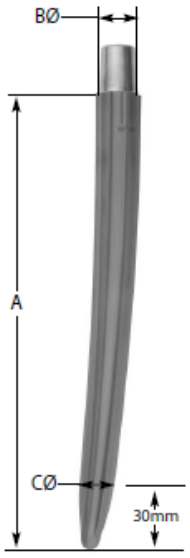


Figure 36

Description	Size	A	BØ	CØ
Tapered Stem Curved	Size 10	175	18	10
Tapered Stem Curved	Size 11	175	18	11
Tapered Stem Curved	Size 12	175	18	12
Tapered Stem Curved	Size 13	175	18	13
Tapered Stem Curved	Size 14	175	18	14
Tapered Stem Curved	Size 15	175	19	15
Tapered Stem Curved	Size 16	175	20	16
Tapered Stem Curved	Size 17	175	21	17
Tapered Stem Curved	Size 18	175	22	18
Tapered Stem Curved	Size 19	175	23	19
Tapered Stem Curved	Size 20	175	24	20
Tapered Stem Curved	Size 21	175	25	21
Tapered Stem Curved	Size 22	175	26	22

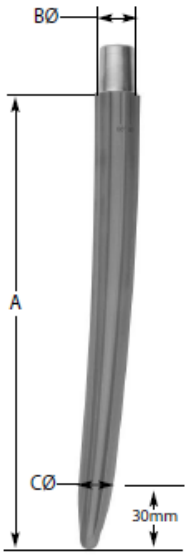


Figure 37

Stems

Tapered Splined Long (Bowed)

Description	Size	A	BØ	CØ
Tapered Stem Curved	Size 10	215	18	10
Tapered Stem Curved	Size 11	215	18	11
Tapered Stem Curved	Size 12	215	18	12
Tapered Stem Curved	Size 13	215	18	13
Tapered Stem Curved	Size 14	215	18	14
Tapered Stem Curved	Size 15	215	19	15
Tapered Stem Curved	Size 16	215	20	16
Tapered Stem Curved	Size 17	215	21	17
Tapered Stem Curved	Size 18	215	22	18
Tapered Stem Curved	Size 19	215	23	19
Tapered Stem Curved	Size 20	215	24	20
Tapered Stem Curved	Size 21	215	25	21
Tapered Stem Curved	Size 22	215	26	22

Adaptors

Description	Length
Length Adaptor	26
Length Adaptor	26
Length Adaptor	26
Length Adaptor	52
Length Adaptor	26

Notes:

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 hydroxyapatite, titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.
(European Union Only) PROFEMUR® R revision hip system is not intended for use in primary arthroplasty.

Contraindications

Patients should be warned of these contraindications.
Contraindications include:

1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4) skeletally immature patients (patient is less than 21 years of age at the time of surgery);
5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6) neuropathic joints;
7) hepatitis or HIV infection;
8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

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

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

Product-Specific Warnings and Precautions

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

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

Other Modular Components

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

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

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

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

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

• Profemur® E Size 0 Hip Stem

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

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

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

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

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

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

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

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

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

IMPORTANT

Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this Surgical Technique and the Instructions For Use package inserts are available on the website listed.

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