Profemur® Xm

Hip System

SURGICAL TECHNIQUE - Profemur® Xm Hip System

MicroPort Orthopedics

Full Function, Faster™

Table of Contents

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 package insert is available on the website listed.

Package inserts can be found under:
Prescribing on ortho.microport.com

Preface

Ordering Information	
Templates	XTR1CL00E
Surgical Technique	011446
Instrument Kits	APH03910 (Profemur® Xm Instrument Kit) APH00000 (Profemur® General Instruments)
Implants	
PXTRKITA	Stems
COCRKITA	Modular Necks
CERAKITA	Ceramic Heads
SUFIKITA	Metal Heads

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

Design Features of the Profemur® Xm Hip System

Surface
Highly polished, forged CoCr stem reduces friction at the cement-implant interface, reducing the potential for wear

Rounded Edges
Promotes radial compressive loading

Sizes
Available in sizes 0-4

Dual Taper Geometry
Promotes cement engagement and provides rotational stability

Distal Centralizers
With or without wings

Allow distal stem engagement within the cement mantle

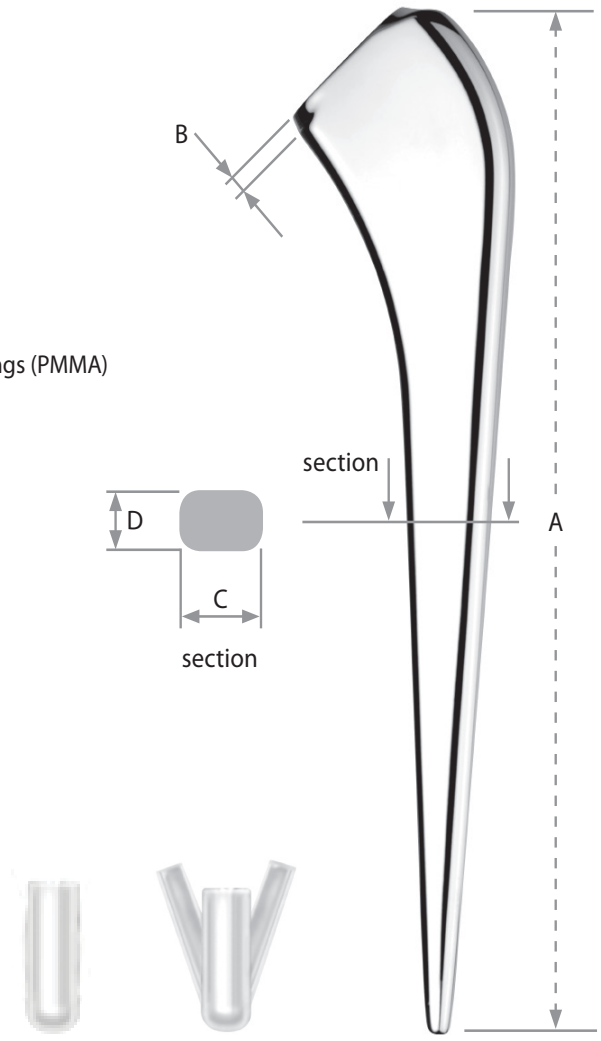
Preface

General Specifications
Profemur® Xm Hip System

Dimensional Chart
Profemur® Xm Hip Stems (Measurements in millimeters)

Size	Lateral Stem Length (A)	Collar Height (B)	M/L Section Width (C)	A/P Section Width (D)
0	133	2.0	10.5	8.6
1	137	2.5	11.5	9.0
2	141	3.0	13.3	9.4
3	145	3.5	15.0	9.9
4	149	4.0	16.7	10.3

- Stems are made of CoCr material
- M/L Section Width: 10.5 – 16.7mm
- A/P Section Width: 8.6 – 10.3mm
- Gamma Sterilization
- Separately packaged centralizers: with or without wings (PMMA)



Chapter 1

PRE OPERATIVE PLANNING

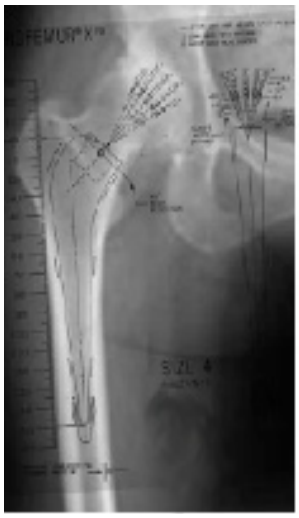


Figure 1

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

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 determined, 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. 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.

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

Chapter 2

Surgical Technique

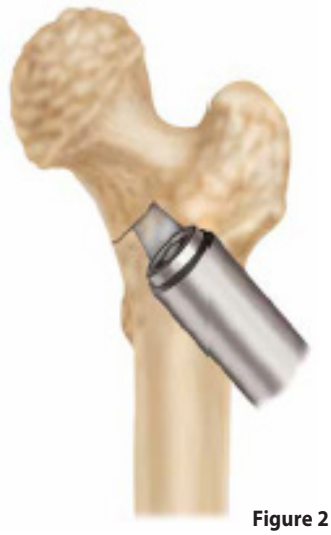


Figure 2

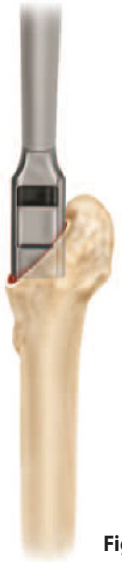


Figure 3

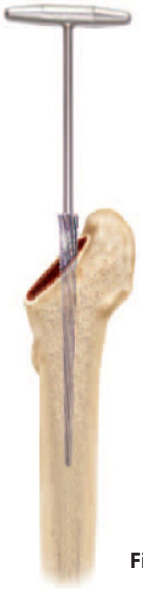


Figure 4

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. **Figure 2**

Femoral Canal Preparation

Using the box chisel (PPR67704-included in APH00000), open the femoral canal. **Figure 3** The box chisel should be lateralized to ensure a neutral orientation of the implant.

Starter Reamer

Enter the femoral canal with the Profemur® X[m] Starter Reamer 1 (APA09052) to prepare the distal part of the femur. Proper reaming depth, measured from the medial resection, corresponds to the templated stem length. Use Starter Reamer 2 (APA09054) to prepare the proximal part, going to the same depth. The reamers show markings illustrating the length of the prosthesis whereas Starter Reamer 2 also includes the length of the centralizer. **Figure 4**

Box Chisel
PPR67704

Starter Reamer 1
APA09052

Starter Reamer 2
APA09054

Figure 5

Figure 6

Starter Broach

After opening the femoral canal, utilize the Starter Rasp 1 (APA09056) to start shaping the femoral canal. Stay centered between the anterior and posterior cortices. Insert the broach using impactions until it rests flat at the level of the neck resection. Repeat with Starter Rasp 2 (APA090SO) **Figure 5**

Femoral Broaching

Attach the broach handle (PPW38078) to the first broach size 0 (APA09000). Using a mallet, with short, controlled strokes, begin broaching. The correct broach depth is achieved when the base of the polished oval collar rests along the resection. Recognize that the polished collar increases in height as stem size increases. Throughout broaching, continue to apply lateral pressure to ensure neutral alignment of the implant. **Figure 6**

Sequentially increase broach size (APA09002-APA09008) until an optimal fit is found. This will be denoted by a change in tone or resistance as the corners of the broach contact the cortical bone of the femur. To verify a secure fit, attempt to rotate the broach, relative to the femur. With proper cortical contact, the broach should not twist or move relative to the femur. At this point, leave the broach fully seated in the canal and detach the broach handle.

Surgical Technique

The broach handle shows a scale to assist in determining the seating of the broach (and therefore the corresponding implant) in relation to the tip of the greater trochanter. The outcome can be compared with the preferred implant size/position determined during pre-planning.

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 braoch 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 braoch motion may clear excess medial and lateral bone. If still tight, the stem should be appropriately downsized untill metaphyseal bone is engaged.

Starter Rasp 1
APA09056

Starter Rasp 2
APA090S0

Broach Handle
PPW38078

Broach
APA09000-09008

Surgical Technique

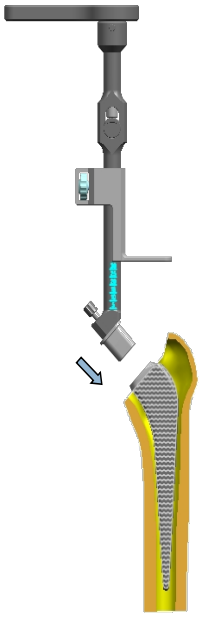


Figure 7

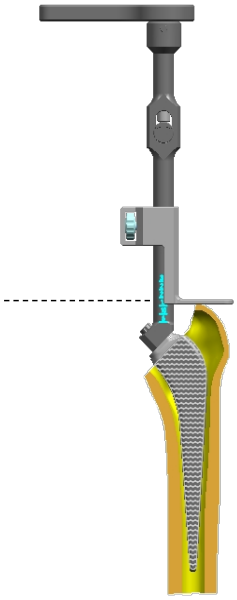


Figure 8

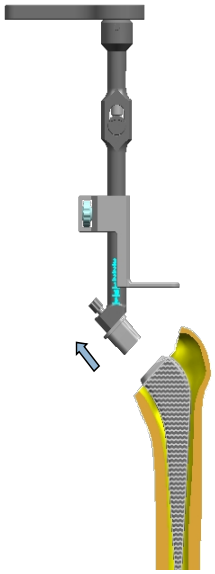


Figure 9

Measurement Broach Seating

To exactly measure the seating of the broach in relation to the greater trochanter, the Depth Gauge (APA09058) can be used in combination with the Stem Positioner (APA09024). **Figure 7**

Attach the support for Stem Positioner (APA09026) to the Stem Positioner and fully insert into the modular neck pocket of the broach. Fixate with the hex screw driver (PP275400) but do not overtighten. **Figure 8**

Slide the Depth gauge (APA09058) down over the Stem Positioner to the level of the greater trochanter and tighten.

Remove the Stem Positioner with tightened seating gauge in place. **Figure 9**

Stem Positioner
APA09024

Support for Stem Positioner
APA09026

Hex Screw Driver
PP275400

Depth Gauge
APA09058

Surgical Technique

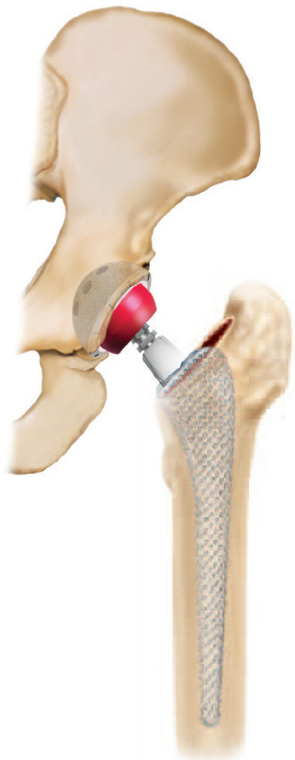


Figure 10

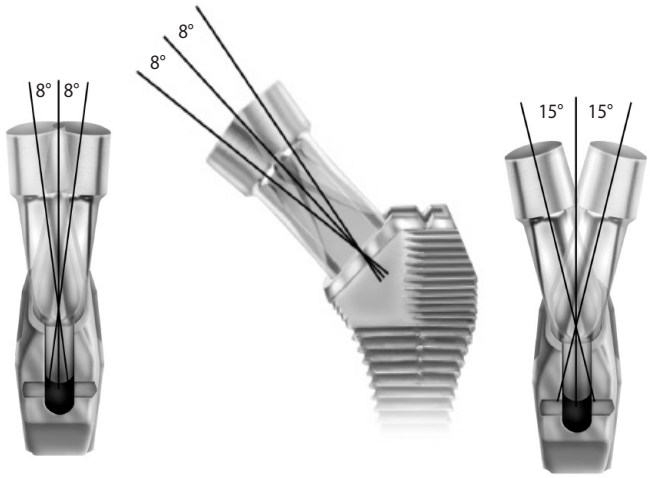


Figure 11

Trial Reduction

Select the appropriate plastic (APA11102-11162) or metal (APA12102-12162) Profemur® Trial Neck and Trial Head and perform a trial reduction. Once a balanced hip has been created with a trial head and trial neck, remove the broach. **Figure 10**

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.

Trial Neck
APA12102-12162

Trial Neck
APA11102 - 11162

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 posteriorly relative to the stem by 8° or 15°.
- Retroverted necks shift the femoral head posteriorly relative to the stem by 8° or 15°. Retroverted necks prove useful in hips with excess femoral anteversion such as DDH.
- AR/VV necks combine anteversion/retroversion and varus/valgus necks to offer a broad range of multi-dimensional head positions. Each AR/VV neck provides 4° of A/R and 6° of V/V. **Figure 11**

Surgical Technique

Figure 12

Figure 13

Stem Insertion

The femoral bone bed is cleaned and the bone cement is prepared and introduced into the femoral canal according to standard recommendations. Each centralizer package contains two distal centralizers (with or without wings). Place the preferred centralizer onto the distal stem – it will fix by applying light pressure. **Figure 12**

Option 1

Place the support for stem positioner (APA09026) **Figure 13** into the modular neck pocket. Using the hex driver (PP275400), connect the support to the femoral implant. Attach the Stem Positioner (APA09054) to the support by pulling back on the quick-release trigger. Release the handle, thereby locking the two components together. Insert the stem into the femoral canal until the seating gauge hits the tip of the greater trochanter, mimicking the seating of the broach.

Having reached the preferred depth of the implant, the final stem positioner is released from the stem by pulling on the quick-release trigger and disengaging the two components. The Final Impactor (APA09028) can be used to stabilize the stem during curing of the cement. After the cement cures and all excess cement is removed, use the hex driver to disconnect the support for stem positioner from the femoral implant.

Note: Do not over-tighten the inserter adaptor to the femoral implant or allow excess cement tocure over the support. Both cases may cause difficulty during support removal.

Support for Stem Positioner
APA09026

Stem Positioner
APA09024

Surgical Technique

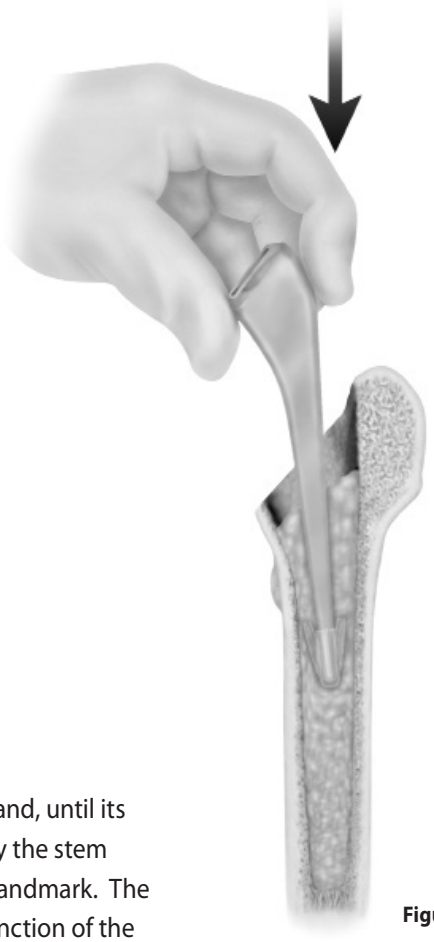


Figure 14

Option 2

Insert the stem into the femoral canal, by hand, until its final depth is reached. **Figure 14** Alternatively the stem can be positioned using the black dot as a landmark. The location of this dot corresponds with the junction of the teeth and the collar on the broach.

The Final Impactor (APA09028) can be used to stabilize the implant during cement curing. After cement cures, remove all excess cement.

Note: Do not allow excess cement to enter the modular neck pocket.

After final implantation, another trial reduction can be performed, using the plastic trial necks and heads, to reconfirm stability, range of motion and leg length.

Final Impactor
APA09028

Surgical Technique

Implant Assembly

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

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

Figure 15

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

Figure 15 & 16

Figure 16

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.

Figure 17

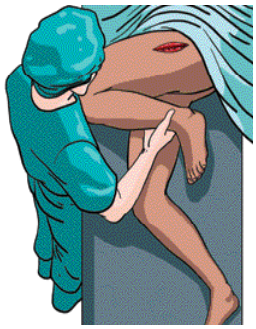


Figure 17

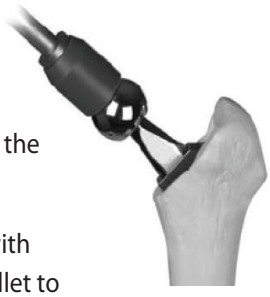


Figure 18

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.

Figure 18

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.

Chapter 3

Implant Removal

Figure 19

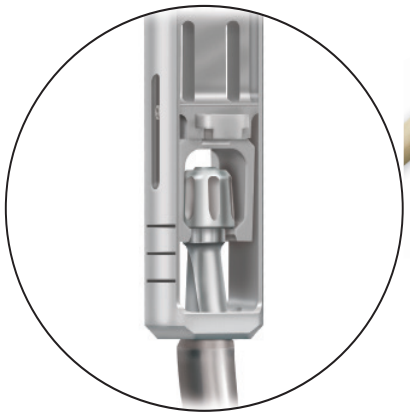


Figure 20

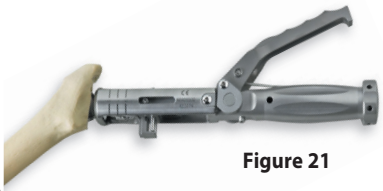


Figure 21

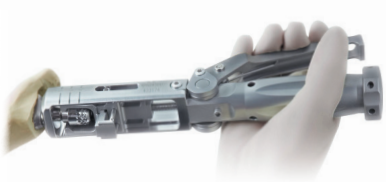


Figure 22

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 19**

Femoral Neck Extraction

Screw the femoral neck adaptor (APA09501) onto the femoral neck in a clockwise motion. **Figure 20** The neck extractor goes over the top of the femoral neck and the adaptor is captured by the adjustable hook. By squeezing the handle an extraction 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.

Modular Stem Removal

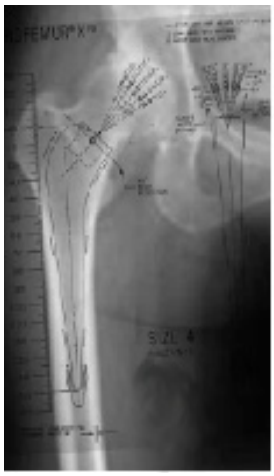
The thread at the base of the modular neck pocket can now be accessed to remove the stem. Insert the Femoral Stem Extractor (PPR67688) **Figure 21** into the modular neck pocket and tighten the threaded shaft by hand, followed by firmly seating the shaft via the use of the Hex Screwdriver (PP275400). Using the slide hammer portion, create extraction forced onto the underside of the femoral stem exctractor strike plate to remove the stem. **Figure 22**
If bone ongrowth exists, it may be necessary to use osteotomes in order to first disengage the stem/bone interface.

Profemur® Modular Necks Extractor Kit
APH04600

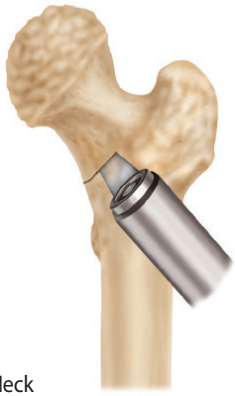
Catalog#	Description
APA09500	Neck Extractor
APA09501	Adaptor 12/14 for Neck Extractor
APA09502	Wrench for Neck Extractor
PP275400	Hex Screwdriver
PRNETR01	PROFEMUR® Neck Extractor Tray
150802 or 130561	PKG Insert Instrument Cleaning

Chapter 4

Technique Overview

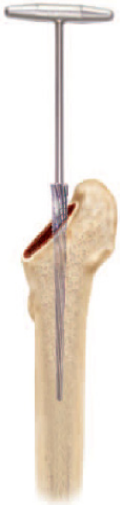


1. X-ray



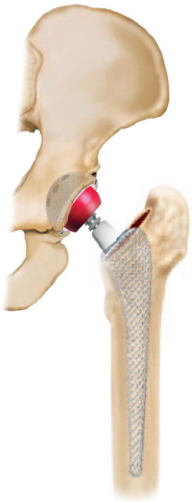
2. Femoral Neck Osteotomy

3. Box Osteotome

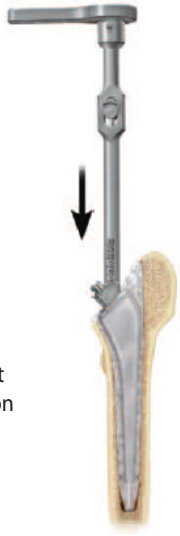


4. Starter Reamer

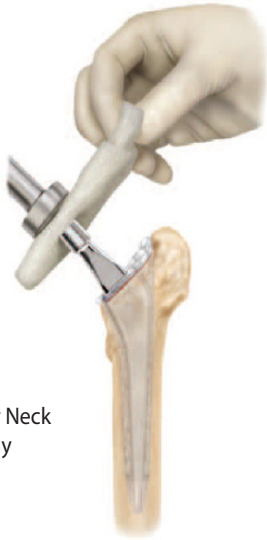
5. Broach and Broach Handle



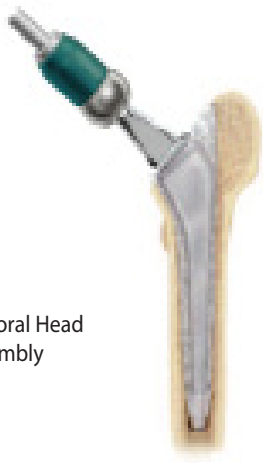
6. Trial Reduction



7. Implant Insertion



8. Modular Neck Assembly



9. Femoral Head Assembly

Chapter 5

Ordering Information

Figure 23

Profemur® X^m Stems
PXTRKITA

Size	Catalog No.
0	PHA06000
1	PHA06002
2	PHA06004
3	PHA06006
4	PHA06008
	PRXMDC01 Distal Centralizers

Profemur® Modular Necks
COCRKITA

Figure 24

Catalog No.	Description
PHA01202	Straight Short (Ti alloy)
PHAC1204	Straight Long (CoCr alloy)
PHA01252	Varus / Valgus 8° Short (Ti alloy)
PHA01232	Ante / Retro 8° Short (Ti alloy)
PHAC1234	Ante / Retro 8° Long (CoCr alloy)
PHA01242	Ante / Retro 15° Short (Ti alloy)
PHAC1244	Ante / Retro 15° Long (CoCr alloy)
PHA01222	Ante / Retro - Varus / Valgus 1 Short (Ti alloy)
PHAC1224	Ante / Retro - Varus / Valgus 1 Long (CoCr alloy)
PHA01212	Ante / Retro - Varus / Valgus 1 Short (Ti alloy)
PHAC1214	Ante / Retro - Varus / Valgus 2 Long (CoCr alloy)

General Instrument Kit
APH00000

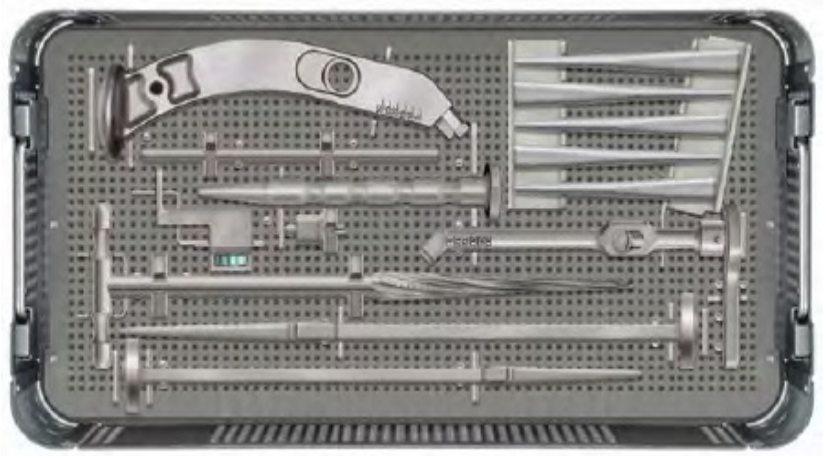
NOTE:
The orientator handle of prosthesis (PPX028960) can be ordered as optional in place of stem guide impactor (APA01114), which is also optional.

Catalog #	Description	
PRGITR01	PROFEMUR® General Tray 1	
PPR67704	Initial Chisel ANCA-FIT™	
PPW36294	Rotation Guide Handle	
PP275400	Hex Screwdriver 3.5mm	
PPW38078	Rasp Handel PROFEMUR® R	
APA00006	Tommy Bar For Cardan Spanner	
PPR67702	Head Impactor	
PPF60200	Final Stem Impactor TMF	
PPG30170	Extraction Ring	
APA11102	PROFEMUR® Trial Neck Short Straight	
APA11104	PROFEMUR® Trial Neck Long Straight	
APA11112	PROFEMUR® Trial Neck Short A/R VAR/VAL 1	
APA11114	PROFEMUR® Trial Neck Long A/R VAR/VAL 1	
APA11122	PROFEMUR® Trial Neck Short A/R VAR/VAL 2	
APA11124	PROFEMUR® Trial Neck Long A/R VAR/VAL 2	
APA11132	PROFEMUR® Trial Neck Short A/R 8º	
APA11134	PROFEMUR® Trial Neck Long A/R 8º	
APA11142	PROFEMUR® Trial Neck Short A/R 15º	
APA11144	PROFEMUR® Trial Neck Long A/R 15º	
APA11152	PROFEMUR® Trial Neck Short VAR/VAL 8º	
APA11154	PROFEMUR® Trial Neck Long VAR/VAL 8º	
APA11162	PROFEMUR® Trial Neck Short VAR/VAL 15º	
APA02121	Femoral Head Trial 28mm S	
APA02122	Femoral Head Trial 28mm M	
APA02123	Femoral Head Trial 28mm L	
APA02124	Femoral Head Trial 28mm XL	
APA02125	Femoral Head Trial 28mm XXL	
APA02131	Femoral Head Trial 32mm S	
APA02132	Femoral Head Trial 32mm M	
APA02133	Femoral Head Trial 32mm L	
APA02134	Femoral Head Trial 32mm XL	
APA02142	Femoral Head Trial 36mm S	
APA02144	Femoral Head Trial 36mm M	
APA02146	Femoral Head Trial 36mm L	
APA02148	Femoral Head Trial 36mm XL	
APA02139	Femoral Head Trial 40mm S	
APA02140	Femoral Head Trial 40mm M	
APA02141	Femoral Head Trial 40mm L	
APA01114	Stem Guide Impactor	Optional
PPX028960	Orientator Handle	Optional
150802 or 130561	PKG Insert Instrument Cleaning	

Profemur® Xm Instruments
APH03910

Catalog #	Description	
APA09000	PROFEMUR® Xm Rasp Size 0	
APA09002	PROFEMUR® Xm Rasp Size 1	
APA09004	PROFEMUR® Xm Rasp Size 2	
APA09006	PROFEMUR® Xm Rasp Size 3	
APA09008	PROFEMUR® Xm Rasp Size 4	
APA09024	Stem Positioner PROFEMUR® Xm	
APA09026	Support for Stem Positioner	
APA090SO	Starter Rasp 2 PROFEMUR® Xm	
APA09028	Final Impacter PROFEMUR® Xm	
APA09052	Distal Reamer 1 PROFEMUR® Xm	
APA09054	Distal Reamer 2 PROFEMUR® Xm	
APA09056	Starter Rasp 1 PROFEMUR® Xm	
APA09058	Depth Gauge PROFEMUR® Xm	
PRXMTR01	PROFEMUR® Xm Tray 1	
XTR1CL00E	PROFEMUR® Xm X-ray Templates	
PPW38078	Rasp Handle PROFEMUR®	Optional
APA00006	Tommy Bar	Optional
150802	PKG Insert Instrument Cleaning	

NOTE:
Profemur® Xm instruments APH03910 must be used with the General Instrument Set APH00000



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

The Profemur® X^{m} Hip Stem is intended for use in cemented 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 (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 product package insert for specific warnings and precautions regarding ceramic femoral heads.

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

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

Modular Necks

- Cobalt Chrome Modular Necks are not for use with the following devices:
  - Alumina (Biolox Forte) "Ceramic Femoral Head" (size 28mm Long)

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.

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

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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Full Function, Faster™

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