Profemur® *TL*

Hip System: Classic and Modular Stems

SURGICAL TECHNIQUE

MicroPort Orthopedics

Full Function, Faster™

Table of Contents

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.

Chapter 1

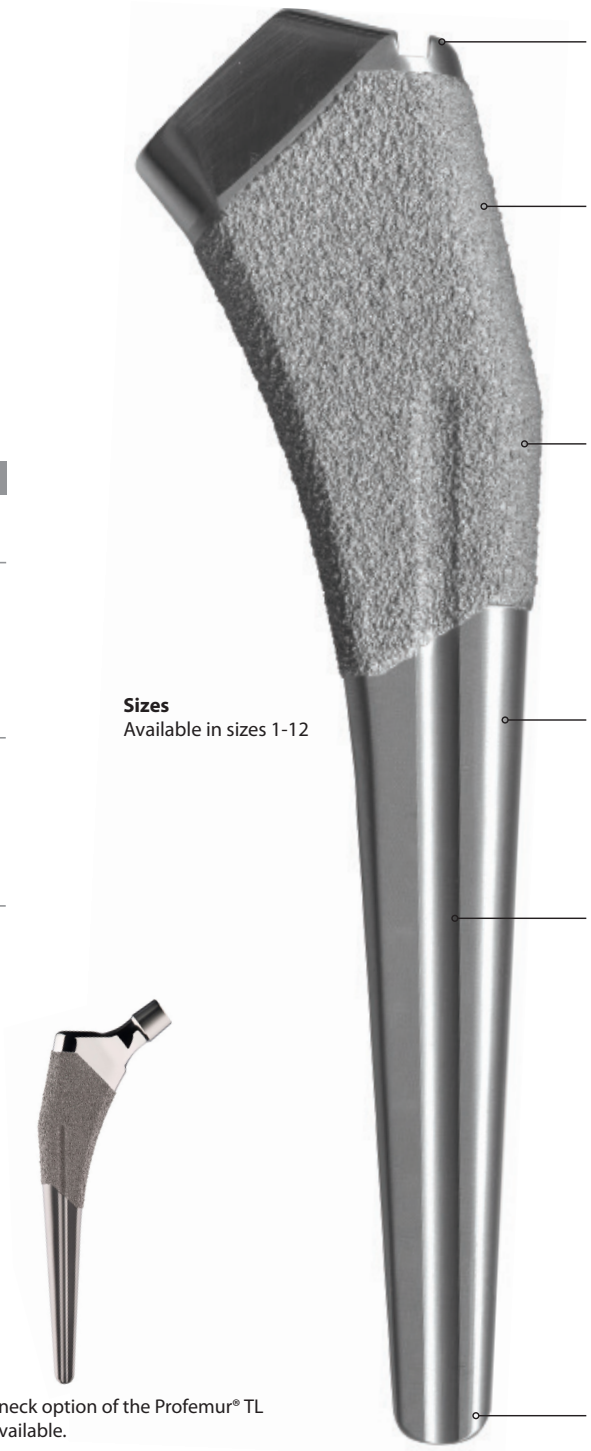
Profemur® TL Stem

Product Information

Design Features

Ordering Information	
Templates	PRTLXR15 (Modular) PTLCXR15 (Classic)
Surgical Technique	010580B
Instrument Kits	PRTLKIT2 (Broaches and Starter Reamer) APH00000 (General Instrument Set)
Implants	PRTLKITA (Modular) TLCLKITS (Classic) SUFIKITA (Metal Heads) CERAKITA (Ceramic Heads) COCRKITA (Modular Necks)

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



Driving Platform
Dimple designed for uni-directional loading during stem insertion, and straight slot designed for rotational control during stem insertion

Lateral Shoulder
Reduced material helps to conserve bone and ease insertion

Ti Plasma Spray
Designed to provide additional 1mm press-fit (0.5mm per side) to assist initial stability

Sizes
Available in sizes 1-12

Titanium Stem Surface
Glass-beaded texture

Distal Groove
Designed to assist rotational stability

Rounded Distal Tip
Shape designed to reduce the risk of fracture during insertion and minimize point contact after implantation

A fixed-neck option of the Profemur® TL is also available.

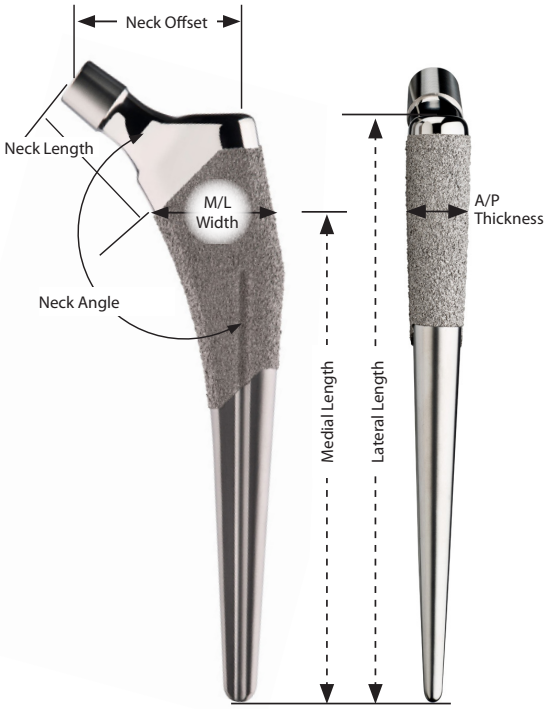
Profemur® TL and Classic Stems General Specifications

- Stems are made of Titanium alloy with commercially-pure Titanium plasma spray over the proximal region (0.5mm/side)
- M/L Width: 27.3 – 39.2mm
- A/P Thickness: 12.8 – 14.7mm
- Classic Straight neck angle is 135°
- Classic Varus 8° Offset neck angle is 127°

Dimensional Chart

Profemur® TL Hip Stems (Measurements in millimeters)

	Short Neck Modular and Classic		Long Neck Modular		Stem Measurements			
Size	Neck Length	Offset	Neck Length	Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
Straight (135°)								
1	29	34	40	41	109	27	13	130
2	29	35	40	42	111	28	13	132
3	29	35	40	43	114	29	13	135
4	34	39	45	46	116	30	13	142
5	34	39	45	46	119	30	13	144
6	34	39	45	47	122	31	14	147
7	34	40	46	48	125	32	14	150
8	35	42	46	49	126	33	14	151
9	35	43	46	50	129	34	14	154
10	35	43	46	51	134	36	14	159
11	35	43	46	51	139	38	14	166
12	35	45	46	53	146	39	15	172
Varus 8° (127°)								
1	30	37	41	45	109	27	13	130
2	30	38	41	46	111	28	13	132
3	30	38	41	47	114	29	13	135
4	35	42	46	50	116	30	13	142
5	35	42	46	50	119	30	13	144
6	35	42	46	51	122	31	14	147
7	35	43	46	52	125	32	14	150
8	36	45	47	53	126	33	14	151
9	36	46	47	54	129	34	14	154
10	36	46	47	55	134	36	14	159
11	36	46	47	55	139	38	14	166
12	36	48	47	57	146	39	15	172



Offset & Neck Length are based on +0 head. Measurements are stem's substrate.
Long Varus Neck option is not available for Profemur® Modular Stems. Information provided for planning purposes.
Profemur® TL Classic long neck stems not available in Europe.

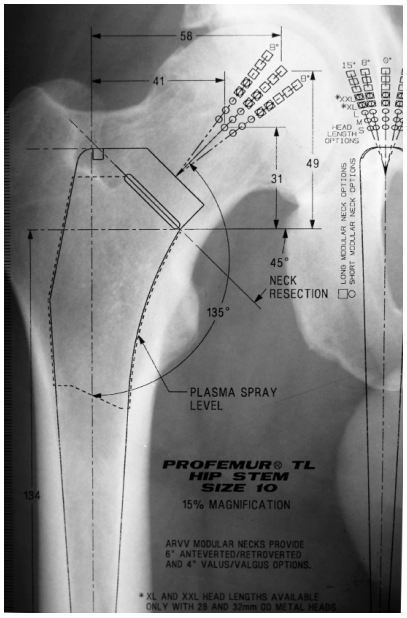
Head Center Adjustment Chart

(Measurements in millimeters)

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

Chapter 2

Preoperative Planning



Preoperative Planning

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

Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip. To determine limb 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. Neck angle and head length which most closely correspond to the patient's femoral head center can be estimated as well. The ideal head will align atop the previously determined center of rotation for the femoral head. In patients with significant deformity of the femoral head, templating can be performed on the opposite hip if necessary.

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

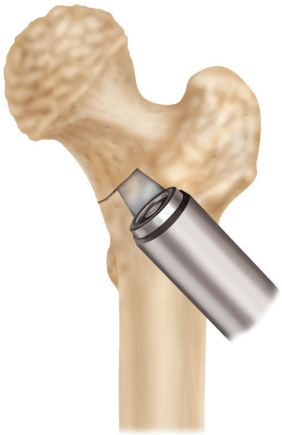
Each circle represents the center of rotation for a modular short neck with the corresponding head option (short to XXlong). Each square represents the center of rotation for a modular long neck with the corresponding head option (short to XXlong). The circles/squares on the AP template of the stem illustrate the impact of choosing an 8° varus/valgus neck relative to the neutral neck position.

The lateral x-ray illustrates the front to back fill of the implant and the position of the implant relative to the femoral anterior bow. If the anterior bow is high, the implant size may be reduced to minimize the risk of fracture. The lateral templates use circles/squares to compare the impact of choosing a neutral neck and necks with 8° or 15° anteversion/retroversion. Both the A/P and lateral views are needed to illustrate the impact of choosing an AR/VV neck because the combination necks provide multi-dimensional positioning. Each AR/VV neck provides 4° anteversion/retroversion and 6° varus/valgus. The impact of each AR/VV option (1 or 2) depends upon which hip is being considered. Therefore, caution should be used to ensure that the appropriate combination is planned.

Chapter 3

Surgical Technique

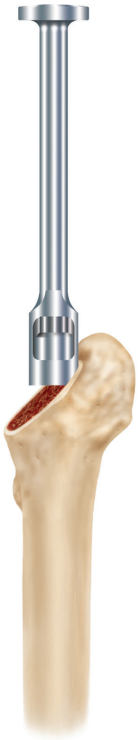
Femoral Neck Osteotomy



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.

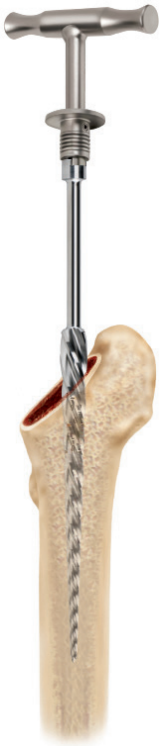
Open the Femoral Canal



Open the Femoral Canal

Using the Profemur® Box Chisel (P/N PPR67704), open the femoral canal. The box chisel should be lateralized to ensure a neutral orientation of the implant.

Profemur® Box Chisel
P/N PPR67704



Starter Reamer

Starter Reamer

Enter the femoral canal with the Profemur® TL Starter Reamer (P/N PRSTREAM). Machined grooves along the surface of the starter reamer indicate the medial lengths of the corresponding broach sizes and reflect the proper depth at which to ream. Attach the Quick Disconnect T-Handle (P/N K0001016) onto the starter reamer, and ream to the appropriate depth according to preoperative templating. The diameter of the reamer is smaller than the corresponding broach at each groove. By stopping the reamer at the appropriate groove, it is assured that the final shape of the femoral canal will be determined by the broach. Manual reaming of the femur using the T-handle is recommended to avoid overreaming the canal, to maintain alignment control and to minimize the amount of heat generated. If powered reaming is preferred, the T-handle can be removed and the starter reamer inserted into a surgical drill.

Profemur® TL Starter Reamer Chart

Implant Size	Medial Implant Length (mm)
1	109
2	111
3	114
4	117
5	119
6	122
7	125
8	126
9	129
10	134
11	139
12	146

Quick Disconnect T-Handle
P/N K0001016

Profemur® TL Starter Reamer
P/N PRSTREAM

Femoral Broaching

Starter Broach

Prepare the femoral canal with the Profemur® TL Broach Size 0 (P/N PRTLBR00). Staying centered between the anterior and posterior cortices, impact the starter broach until the top of the teeth rests just at or below the level of the neck resection.

Femoral Broaching

Attach the Broach Handle (P/N PPW38078) to the size 1 Profemur® TL broach (P/N PRTLBR01). Using a mallet, with short, controlled strokes begin broaching. Sequentially increase the broach sizes while broaching (PRTLBR01-PRTLBR12). Throughout broaching, continue to apply lateral pressure to ensure neutral alignment of the implant.

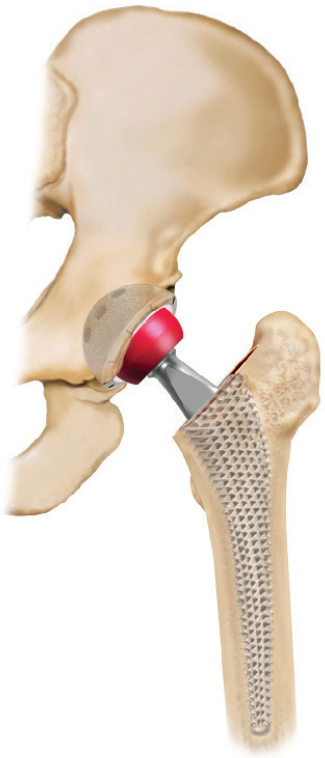
Continue broaching until an optimal fit is found. This will be denoted by a change in tone or resistance as the rounded corners of the broach contact the cortical bone of the femur. To verify a secure fit, attempt to rotate the broach relative to the femur. With proper cortical contact, the broach should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

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.

Broach Handle
P/N PPW38078

Profemur® TL Broach Size 0
P/N PPRTLBR00

Profemur® TL Broach
P/N PPRTLBR01-PRTLBR12



Trial Reduction

Potential Differences Between Broached and Templated Sizes:

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

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

3. If a broach is going in straight and still becomes tight with sizes smaller than templated, a repetitive in/out broach motion may clear excess medial and lateral bone. If still tight, the stem should be appropriately downsized until metaphyseal bone is engaged.

Trial Reduction

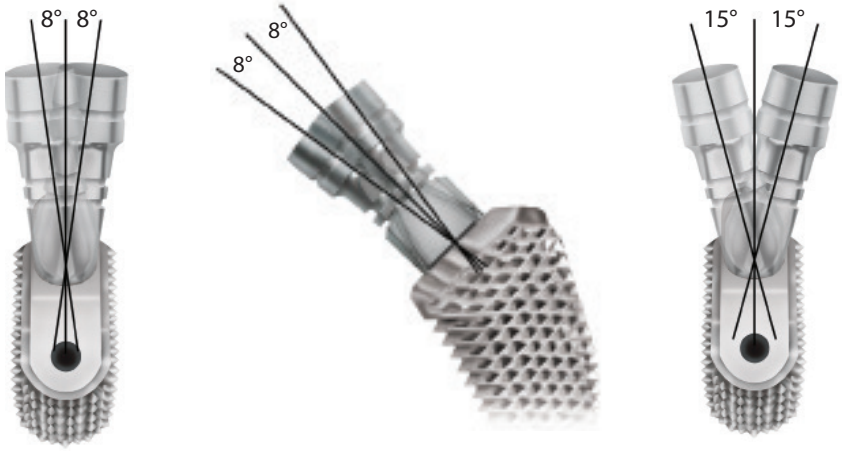
Select the appropriate Profemur® trial neck (APA11102-APA11154, included in APH00000) and trial head (APA02121-APA02154, included in APH00000) and perform a trial reduction. Once a well-balanced hip has been created with a trial head and trial neck, remove the broach.

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.

When implanting a Profemur® TL Classic Short Neck, the trial necks to be used are Straight Short (APA11102) for the Straight option and Varus 8° Short (APA11152) for the Varus 8° option.

Femoral Trial Head
P/N APA02144

Profemur® Long Neutral Trial Neck
P/N APA11104



Summary of Profemur® TL Modular Neck Angle Options

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

»» Straight necks create a neutral neck axis.

»» 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˚.

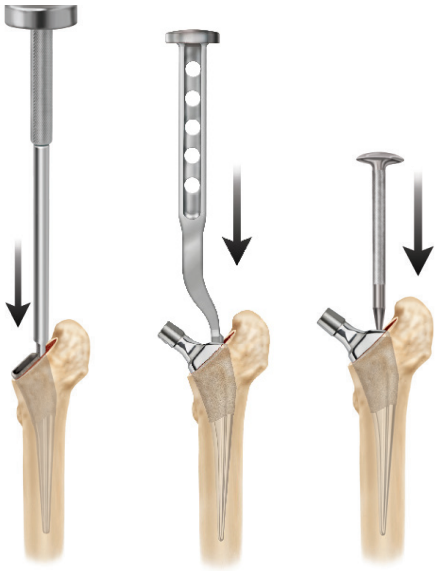
»» Retroverted necks shift the femoral head posteriorly relative to the stem by 8˚ or 15˚. Retroverted necks prove useful in hips with excess femoral anteversion such as DDH.

»» AR/VV necks combine anteversion/retroversion and varus/valgus necks to offer a broad range of multi-dimensional head positions. Each AR/VV neck provides 4˚ of A/R and 6˚ of V/V.

Summary of Profemur® TL Classic Neck Angle Options

»» Straight (135°) necks create a neutral neck axis.

»» Varus 8° necks decrease the inclination angle to 127˚; the femoral head shifts medially and inferiorly; leg length is shortened; offset is increased.



Stem Insertion

Insert the femoral implant into the canal and seat it as far as possible by hand while maintaining proper version. For the modular stems, place the slotted Profemur® Screwdriver Inserter (P/N PRFS0460) into the slot on the proximal face and, with a mallet, fully seat the implant using short, controlled strokes.

For the Classic stems, use the Profemur® Classic Stem Impactor (P/N PRCLIMPT) to engage the oval slot on the lateral shoulder for rotational control. Then, use the Final Stem Impactor (P/N PPF60200) to engage the dimple on the lateral shoulder and apply uni-directionally load. Fully seat the implant using short, controlled strokes with a surgical mallet. Typically, the implant is seated with the base of the polished neck or the underside of the collar at the resection cut.

The implant may sit 1-2mm 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 femoral head.

Final Trial Reduction

Perform a final reduction using plastic trial necks and trial heads to reconfirm stability, range of motion and leg length.

Profemur® Classic Stem Inserter
P/N PRCLIMPT

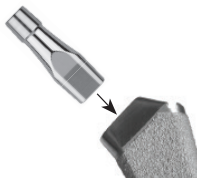
Final Stem Impactor
P/N PPF60200

Profemur® Screwdriver Inserter
P/N PRFS0460

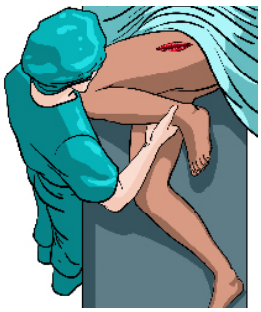
Implant Assembly

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

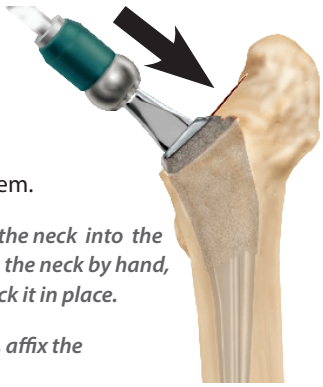
STEP A. Suction any fluid from the stem implant pocket. Ensure that both the stem and neck are clean and dry prior to assembly.



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



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



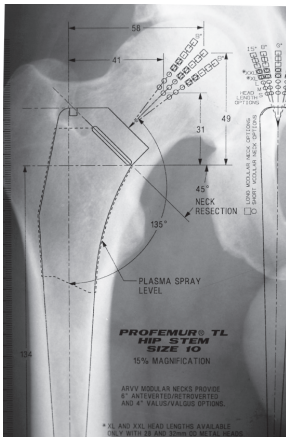
STEP D. Affix the femoral head to the neck. Using the head impactor instrument, strike the impactor with three very firm blows with a mallet to securely fix the head to the neck and stem.

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

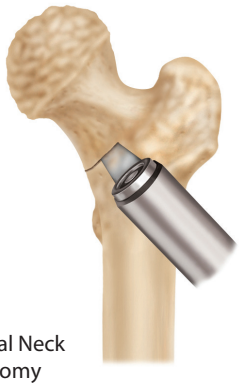
NOTE: *If using a Profemur® TL Classic stem, affix the femoral head to the neck.*

Chapter 4

Technique Overview

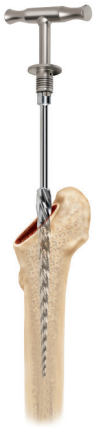


1. X-ray



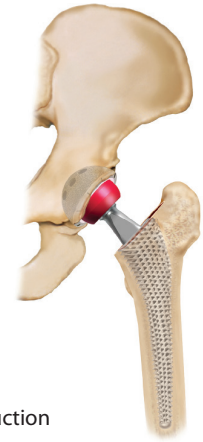
2. Femoral Neck Osteotomy

3. Open the Femoral Canal

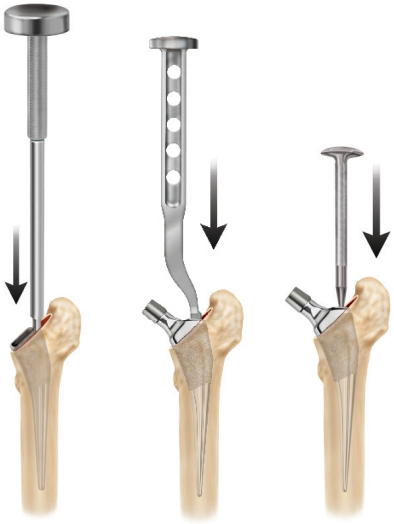


4. Starter Reamer

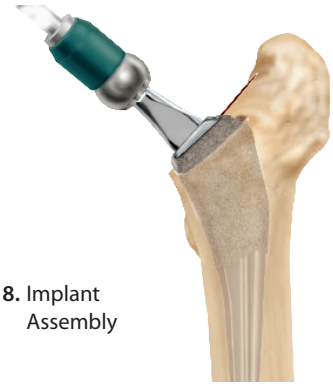
5. Femoral Broaching



6. Trial Reduction

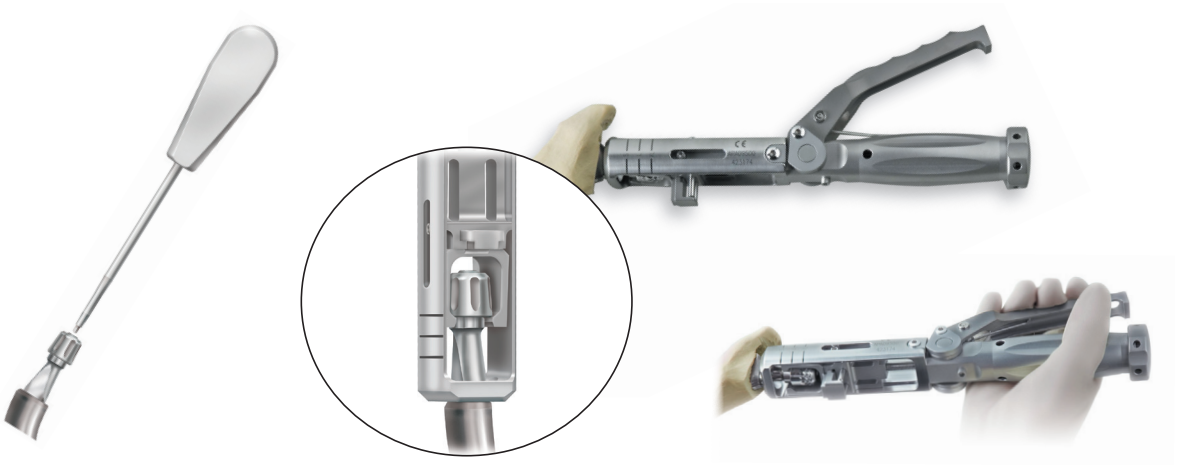


7. Stem Insertion



8. Implant Assembly

Implant Removal



If the removal of the implant is required due to revision, the surgeon should call the number on the back page of this surgical technique and select the option for customer service 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.

Femoral Neck Extraction

Screw the femoral neck adaptor (APA09501) onto the femoral neck in a clockwise motion. The neck extractor 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.

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
130561/150802	Package Insert Instrument Cleaning

Profemur® TL Classic Stem Removal

Stem Removal

Stem Removal

Should the removal of a Profemur® Classic stem become necessary, the Perfecta® Universal Stem Extractor (P/N 4700SE05) and the corresponding Slap Hammer (P/N 4700SH0000) can be utilized. Thread the stem extractor onto the threaded end of the slap hammer. With the femoral head removed, position the stem extractor across the flats on the sides of the femoral neck, and remove the stem using repetitive upward blows delivered by the slap hammer.

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

PERFECTA® Universal Stem Extractor
P/N 4700SE05

Slap Hammer
P/N 4700SH0000

Chapter 5

Ordering Information

Profemur® TL Classic Stems

TLCLKITS

Profemur® TL Classic Stems with Short Necks

Catalog No.	Description	Size
PRTLS021	Straight	1
PRTLS022	Straight	2
PRTLS023	Straight	3
PRTLS024	Straight	4
PRTLS025	Straight	5
PRTLS026	Straight	6
PRTLS027	Straight	7
PRTLS028	Straight	8
PRTLS029	Straight	9
PRTLS030	Straight	10
PRTLS031	Straight	11
PRTLS032	Straight	12
PRTLE021	Varus 8˚	1
PRTLE022	Varus 8˚	2
PRTLE023	Varus 8˚	3
PRTLE024	Varus 8˚	4
PRTLE025	Varus 8˚	5
PRTLE026	Varus 8˚	6
PRTLE027	Varus 8˚	7
PRTLE028	Varus 8˚	8
PRTLE029	Varus 8˚	9
PRTLE030	Varus 8˚	10
PRTLE031	Varus 8˚	11
PRTLE032	Varus 8˚	12

Profemur® TL Stems

PRTLKITA

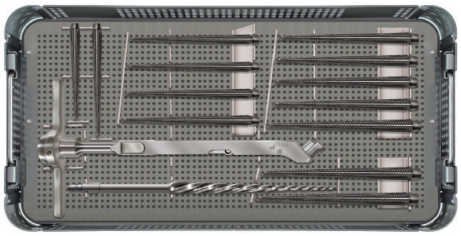
Catalog No.	Stem Size
PRTL0021	1
PRTL0022	2
PRTL0023	3
PRTL0024	4
PRTL0025	5
PRTL0026	6
PRTL0027	7
PRTL0028	8
PRTL0029	9
PRTL0030	10
PRTL0031	11
PRTL0032	12

Profemur® Modular Necks

COCRKITA

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 2 Short (TI Alloy)
PHAC1214	AAnte / Retro - Varus / Valgus 2 Long (COCR Alloy)

Instruments



PRTLKIT2

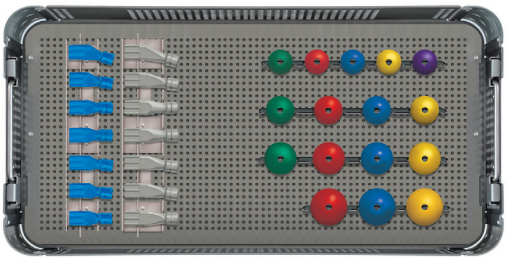
Profemur® TL Instruments

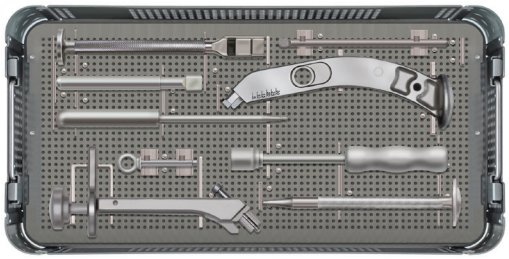
Catalog No.	Description
PRTLBR00	Profemur® TL Broach Size 0
PRTLBR01	Profemur® TL Broach Size 1
PRTLBR02	Profemur® TL Broach Size 2
PRTLBR03	Profemur® TL Broach Size 3
PRTLBR04	Profemur® TL Broach Size 4
PRTLBR05	Profemur® TL Broach Size 5
PRTLBR06	Profemur® TL Broach Size 6
PRTLBR07	Profemur® TL Broach Size 7
PRTLBR08	Profemur® TL Broach Size 8
PRTLBR09	Profemur® TL Broach Size 9
PRTLBR10	Profemur® TL Broach Size 10
PRTLBR11	Profemur® TL Broach Size 11
PRTLBR12	Profemur® TL Broach Size 12
PRSTREAM	Profemur® TL Starter Reamer
BROHANTL	T Broach Handle

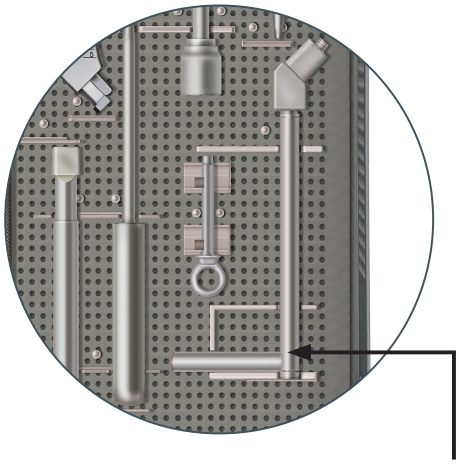
Note: *Profemur® TL instruments PRTLKIT2 must be used with the General Instrument Set APH00000 and PRFS0460 (Profemur® Screwdriver Inserter)*

Stem Impactors

Catalog No.	Description
PRCLIMPT	Profemur® Classic Stem Inserter
PPF60200	Final Stem Impactor







Note: *The orientator handle of prosthesis (PPX028960) can be ordered as optional in place of stem guide impactor (APA01114).*

Instruments

APH00000

Profemur® General Instrument Kit

Catalog No.	Description	
PPR67704	Initial Chisel Anca-Fit™	
PPW36294	Rotation Guide Handle	
PP275400	Hex Screwdriver 3.5mm	
PPW38078	Rasp Handle 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 Long A/R VAR/VAL 2	
APA11124	Profemur® Trial Neck Long A/R VAR/VAL 2	
APA11132	Profemur® Trial Neck Long 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 32mm S	
APA02144	Femoral Head Trial 32mm M	
APA02146	Femoral Head Trial 32mm L	
APA02148	Femoral Head Trial 32mm XL	
APA02139	Femoral Head Trial 32mm S	
APA02140	Femoral Head Trial 32mm M	
APA02141	Femoral Head Trial 32mm L	
APA01114	Stem Guide Impactor	Optional
PPX028960	Orientator Handle	Optional
130561/150802	Package Insert Instrument Cleaning	

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

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

Contraindications

Patients should be warned of these contraindications. Contraindications include:

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

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

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.

MicroPort Orthopedics

Full Function, Faster™

MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN USA 38002
866.872.0211

EC REP

MicroPort Orthopedics BV
Hoogoorddreef 5
1101 BA Amsterdam
The Netherlands
+31 20 545 01 00

ortho.microport.com

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

010580B_Apr´16