

Profemur® L

Total Hip System: Classic and Modular Stems



Table of Contents

Chapter 1	Product Information
2	Design Features: Profemur® L Stems
3	Design Features: Profemur® L Revision Stem
4	Implant Specifications
Chapter 2	Preoperative Planning
Chapter 3	Surgical Technique
6	Femoral Neck Osteotomy
6	Femoral Canal Preparation
6	Femoral Broaching
8	Trial Reduction
9	Stem Insertion - Modular
10	Stem Insertion - Classic
11	Final Trial Reduction
Chapter 4	Implant Removal
12	Femoral Head Removal
12	Femoral Neck Extraction
13	Modular Stem Removal
13	Classic Stem Removal
Chapter 5	Technique Overview
Chapter 6	Ordering Information
15	Profemur® L Stems
15	Profemur® L Revision Stems
16	Profemur® Modular Necks
16	Profemur® L Classic Stems
17	Instruments
Chapter 7	Indications and Warnings

MicroPort Orthopedics recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience and patient condition. Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this Surgical Technique and the Instructions For Use package inserts are available on the website listed.

Please contact your local MicroPort Orthopedics representative/distributor for product availability.

Chapter 1

Profemur® L Stems

Product Information

Design Features

Ordering Information	
Templates	CRL1CL02E (Modular) CRL1CL03E (Classic)
Surgical Technique	010485
Instruments	APH00000 General Instr. Set APH03710 Profemur® L Rasps APH03703 consists of Profemur™ L primary stem instruments (APH3710) and revision rasps with inner tray
Implants	PRFLKITA Primary Stems COCRKITA Modular Necks PRFLKITD Classic Stems SUFIKITA Metal Heads CERAKITA Ceramic Heads

Stem Material
Titanium Alloy (Ti6Al4V) and HA coating, thickness [µm] 180 +/- 50

Dual Taper Geometry
Provides optimal primary fixation and load transfer

Profemur® L Classic Neck Options include Standard (135° CCD) and Extended (127° CCD) neck angles allowing for multiple head center positions to meet range of anatomical needs

Driving Platform
Threaded slot designed for rotational control during stem insertion

Lateral Shoulder
On anterior, posterior and medial sides, the surface presents grooves perpendicular to stem longitudinal axis and parallel with each other, providing a larger bone-stem contact surface for bone on-growth

Distal Rectangular Section and Grooves
Parallel to the stem longitudinal axis on all sides are designed to protect the stem against rotational stresses

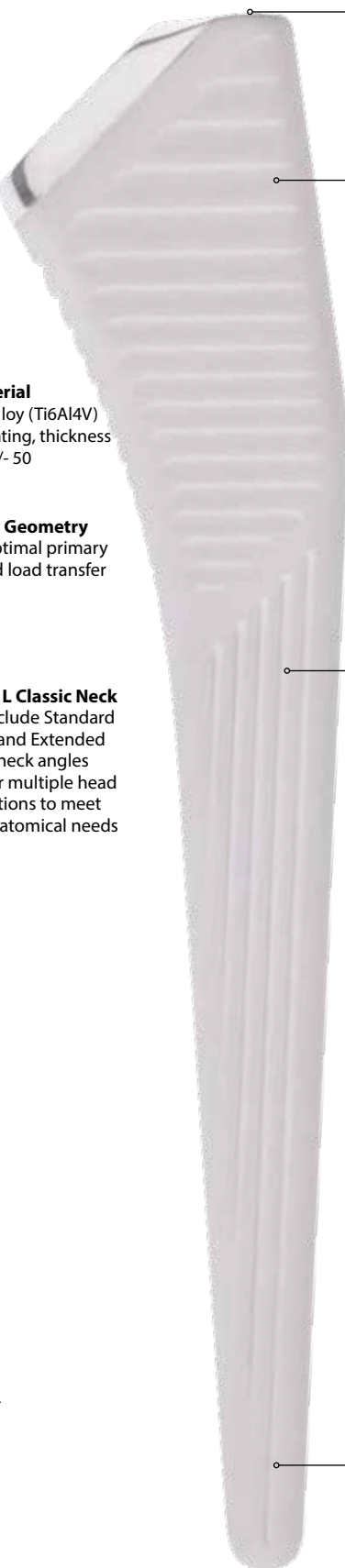
Sizes
The Profemur® L Primary Stem is available in sizes 1-11

Rounded Distal Tip
To minimize point contact in the thigh for comfort

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



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



Profemur® L Revision Stem

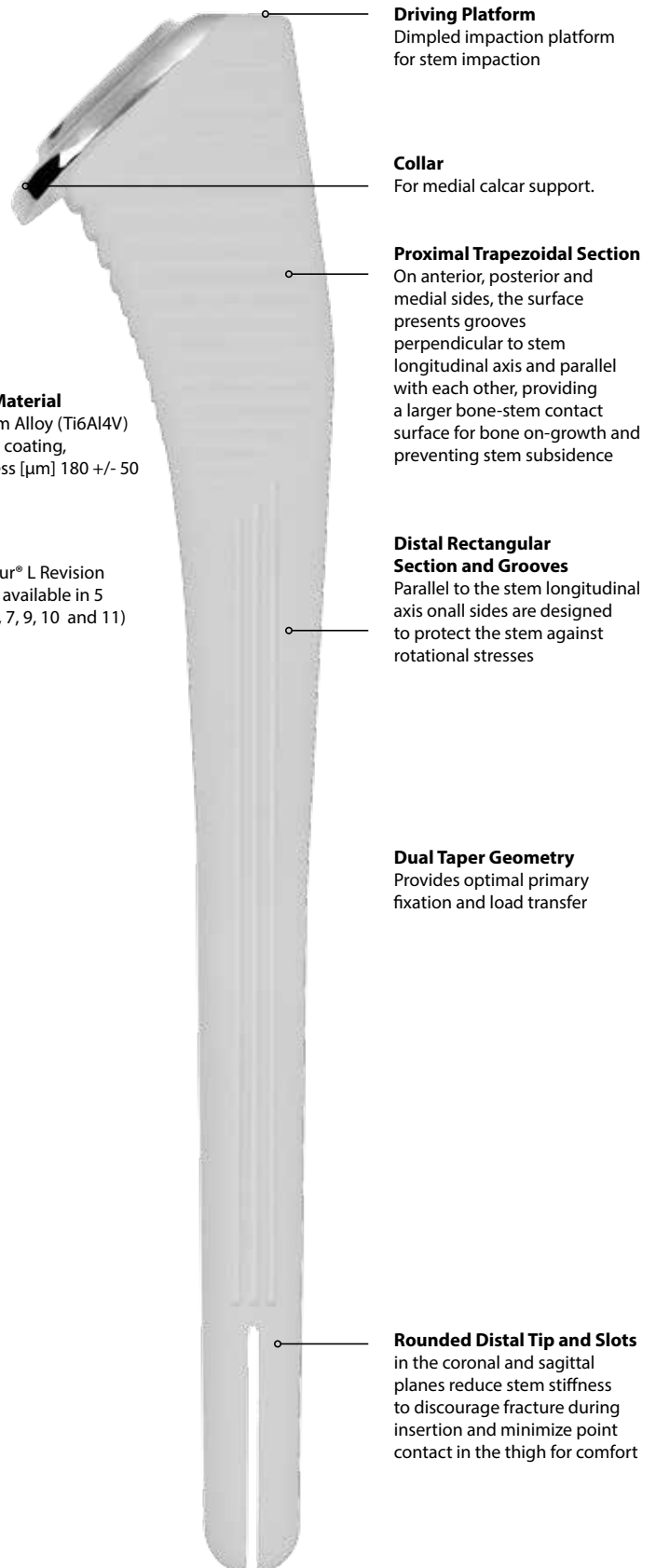
Design Features

Ordering Information	
Templates	CRL1CL02E
Surgical Technique	010485
Instruments	APH00000 General Instr. Set APH03701 L Revision Rasps APH03703 consists of Profemur® L primary stem instruments (APH3710) and revision rasps with inner tray
Implants	PRFLKITB Revision Stems COCRKITA Modular Necks SUFIKITA Metal Heads CERAKITA Ceramic Heads

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

Stem Material
Titanium Alloy (Ti6Al4V) and HA coating, thickness [µm] 180 +/- 50

Sizes
Profemur® L Revision Stem is available in 5 sizes (5, 7, 9, 10 and 11)



Driving Platform
Dimpled impaction platform for stem impaction

Collar
For medial calcar support.

Proximal Trapezoidal Section
On anterior, posterior and medial sides, the surface presents grooves perpendicular to stem longitudinal axis and parallel with each other, providing a larger bone-stem contact surface for bone on-growth and preventing stem subsidence

Distal Rectangular Section and Grooves
Parallel to the stem longitudinal axis on all sides are designed to protect the stem against rotational stresses

Dual Taper Geometry
Provides optimal primary fixation and load transfer

Rounded Distal Tip and Slots
in the coronal and sagittal planes reduce stem stiffness to discourage fracture during insertion and minimize point contact in the thigh for comfort

Implant Specifications

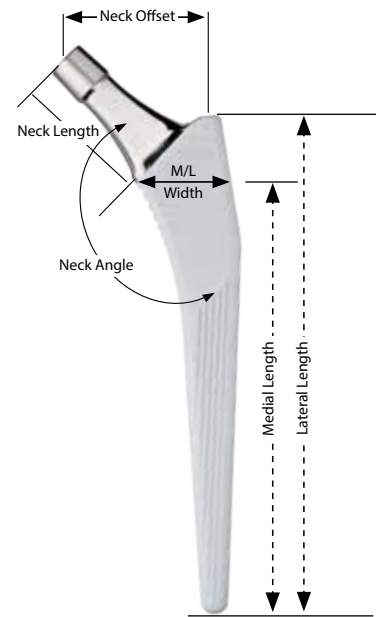
General Specifications

- Titanium material
- Medial Length: 93.5-168.5mm
- M/L Width: 27-37mm
- A/P Thickness: 11.5-16.5mm
- Classic Straight neck angle is 135°
- Classic Varus 8° neck angle is 127°

Dimensional Chart

Profemur® L Primary Hip Stems (Measurements in millimeters)

Size	Short Neck Modular		Medium Neck Classic		Long Neck Modular		Stem Measurements			
	Neck Length	Offset	Neck Length	Offset	Neck Length	Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
Straight (135°)										
1	28	31	35	36	39	39	93.5	27.0	11.5	112.3
2	28	32	35	37	39	39	108.5	27.0	11.5	127.3
3	29	33	36	38	39	41	118.5	27.0	12.0	137.6
4	29	34	36	39	40	41	123.5	28.0	12.5	142.9
5	30	35	37	40	40	42	128.5	29.0	13.0	148.2
6	30	36	37	41	41	43	133.5	30.0	13.5	153.5
7	31	37	38	42	41	44	138.5	31.5	13.5	158.8
8	31	38	38	43	42	45	143.5	32.5	14.0	164.1
9	32	39	39	44	42	46	148.5	33.5	14.0	169.4
10	32	40	39	45	43	48	158.5	35.0	15.5	179.7
11	33	42	40	47	43	49	168.5	37.0	16.5	190.0
Varus 8° (127°)										
1	29	34	40	43	40	43	93.5	27.0	11.5	112.3
2	29	35	40	43	40	43	108.5	27.0	11.5	127.3
3	30	36	40	44	40	45	118.5	27.0	12.0	137.6
4	30	37	41	45	41	45	123.5	28.0	12.5	142.9
5	31	38	41	46	41	46	128.5	29.0	13.0	148.2
6	31	39	42	47	42	47	133.5	30.0	13.5	153.5
7	32	40	42	48	42	48	138.5	31.5	13.5	158.8
8	32	41	43	49	43	49	143.5	32.5	14.0	164.1
9	33	42	43	50	43	50	148.5	33.5	14.0	169.4
10	33	43	44	52	44	52	158.5	35.0	15.5	179.7
11	34	45	44	53	44	53	168.5	37.0	16.5	190.0

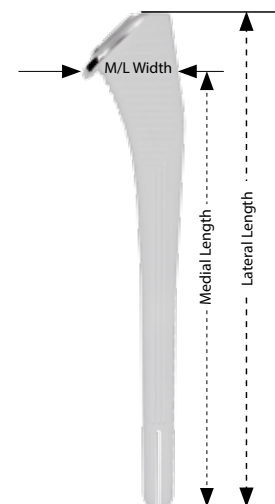


Offset & Neck Length are based on +0 head.
Measurements are stem's substrate.

Dimensional Chart

Profemur® L Revision Hip Stems (Measurements in millimeters)

Size	Short Neck Modular		Long Neck Modular		Stem Measurements			
	Neck Length	Offset	Neck Length	Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
Straight (135°)								
5	30	35	40	42	160.0	29.0	13.0	180.0
7	31	37	41	44	180.0	31.0	14.0	200.0
9	32	39	42	46	189.0	33.5	14.0	210.0
10	32	40	43	48	198.5	35.0	15.5	220.0
11	33	42	43	49	218.5	37.0	16.5	240.0
Varus 8° (127°)								
5	31	38	41	46	160.0	29.0	13.0	180.0
7	32	40	42	48	180.0	31.0	14.0	200.0
9	33	42	43	50	189.0	33.5	14.0	210.0
10	33	43	44	52	198.5	35.0	15.5	220.0
11	34	45	44	53	218.5	37.0	16.5	240.0



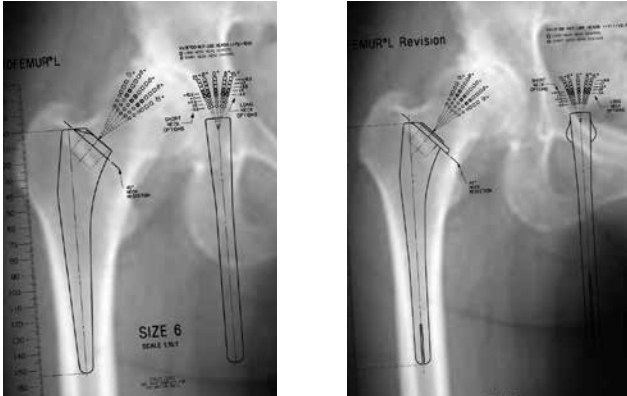
Offset & Neck Length are based on +0 head.
Measurements are stem's substrate.

Head Adjustment Chart (Measurements in millimeters)

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

Chapter 3

Preoperative Planning



Preoperative Planning

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 4

Surgical Technique



Femoral Neck Osteotomy

Approximately 10 - 20mm below the greater trochanter, resect the neck at a 45° angle to the longitudinal axis of the femur.

Femoral Canal Preparation

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

NOTE: In case the PROFEMUR® L Revision is to be implanted, remove carefully the failed implant and any remaining cement or other debris in the femoral canal before you start broaching.

Femoral Broaching

Attach the Broach Handle (PPW38078) to the size 1 Profemur® L broach (APA07502) or to the size 5 Profemur® L Revision broach (APA07564). Using a mallet with short, controlled strokes, begin broaching.

Sequentially increase the broach sizes while broaching (APA07502 - APA07522 for Profemur® L and APA07564 - APA07572 for Profemur® L Revision). Throughout broaching, continue to apply lateral pressure to ensure neutral alignment of the implant.



Box Chisel
P/N PPR67704



Broach Handle
PPW38078



Profemur® L Broach
P/N APA07502-APA07522



Profemur® L Revision Broach
P/N APA07564-APA07572

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.

Potential differences between broaches and templated sizes:

- 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.
- 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.
- If a broach is going in straight and becomes tight with sizes smaller than those 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 (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® L Classic, the trial necks to be used are Straight (APA11170) for the Standard option and Extended (APA11172) for the Extended option.

Brief Summary of Neck Options for Profemur® L Modular:

- 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 multi-dimensional head positions. Each AR/VV neck provides 4° of A/R and 6° of V/V.

Brief Summary of Profemur® L Classic Short Neck:

- Standard (135°) necks create a neutral neck axis.
- Extended necks decrease the inclination angle to 127°; the femoral head shifts medially and inferiorly; leg length is shortened; offset is increased.



Trial Neck
P/N APA11102-APA11154



Trial Neck
P/N APA11170-72



Stem Insertion - Modular

The stem is inserted with the special Stem Inserter (APA01114, included in APH00000). Use the hex screwdriver (PP275400, included in APH00000) to fix the implant in the impactor. The Final Stem Impactor (PPF60200, included in APH00000) is used for final seating of the component. Place the tip of the Final

Stem Impactor into the dimple on the lateral shoulder and, with a mallet, fully seat the implant using short, controlled strokes. Typically, the implant is seated with the base of the polished neck at the resection cut.





Stem Insertion - Classic

Insert the femoral implant into the canal and seat it as far as possible by hand while maintaining proper version. Place the tip of the Final Stem Impactor (PPF60200, included in the APH00000) into the dimple on the lateral shoulder and, with a mallet, fully seat the implant using short, controlled strokes.

Typically, the implant is seated with the base of the polished neck at the resection cut.

Final 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 and trial head 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.

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.

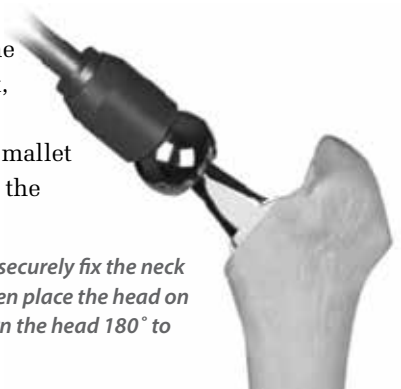
STEP C. Position the leg such that the knee is supported by an assistant on the opposite side of the table. By resting the patient's knee against the mid-section of the assistant, this will provide counter-force against the mallet blows to ensure the impaction load transfer to the neck junction.



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® L® Classic stem, affix the femoral head to the neck.



Chapter 3

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



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) 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 forces onto the underside of the femoral stem extractor strike plate to remove the stem. If bone on-growth exists, it may be necessary to use osteotomes in order to first disengage the stem/bone interface.



Classic Stem Removal

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



Femoral Stem Extractor
PPR67688



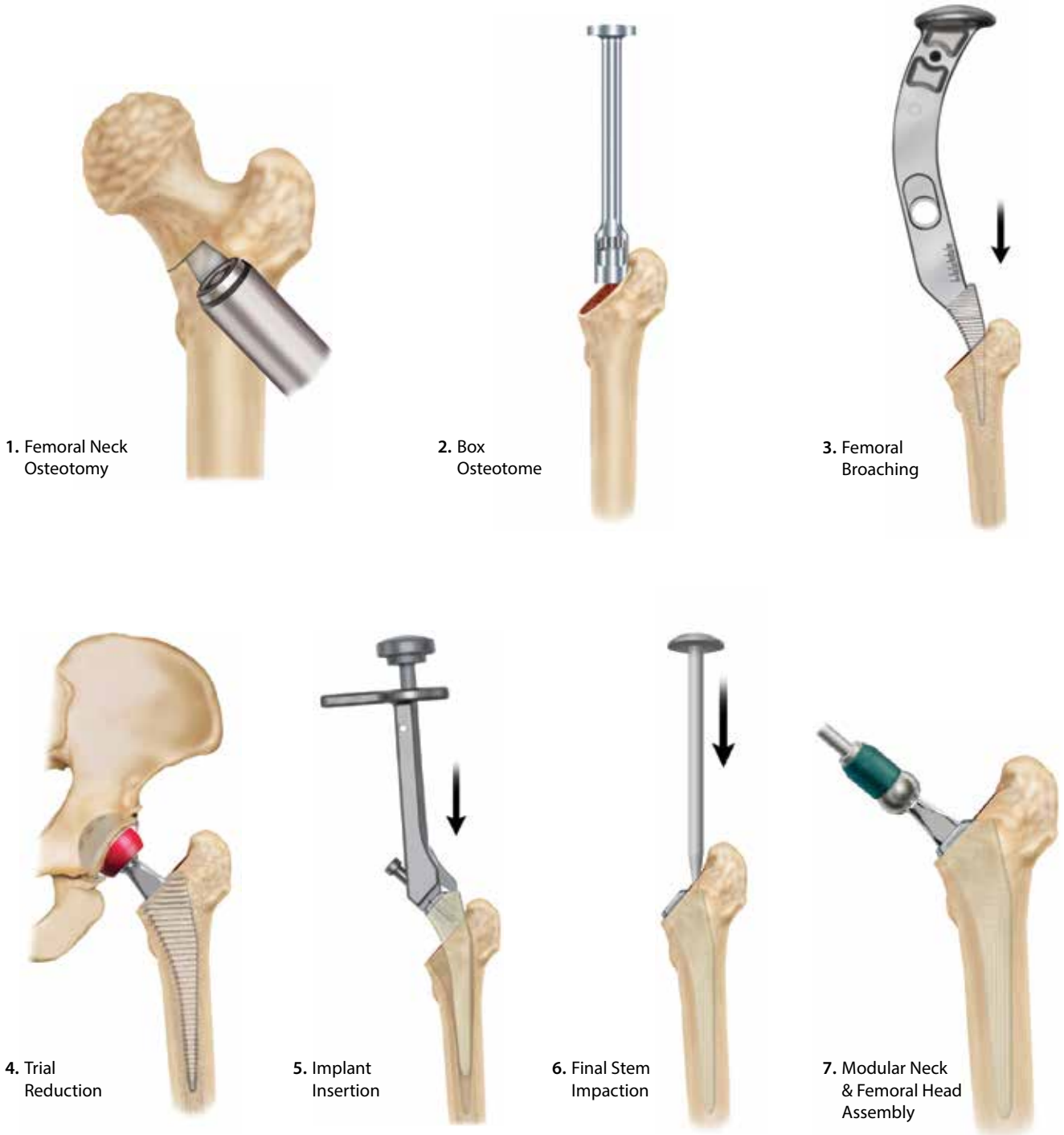
PERFECTA® Universal Stem Extractor
4700SE05



Slap Hammer
4700SH0000

Chapter 5

Technique Overview



Chapter 6

Ordering Information



Profemur® L Stems

PRFLKITA

Catalog No.	Description	Size
PHA05502	PROFEMUR® L Stem	Size 1
PHA05504	PROFEMUR® L Stem	Size 2
PHA05506	PROFEMUR® L Stem	Size 3
PHA05508	PROFEMUR® L Stem	Size 4
PHA05510	PROFEMUR® L Stem	Size 5
PHA05512	PROFEMUR® L Stem	Size 6
PHA05514	PROFEMUR® L Stem	Size 7
PHA05516	PROFEMUR® L Stem	Size 8
PHA05518	PROFEMUR® L Stem	Size 9
PHA05520	PROFEMUR® L Stem	Size 10
PHA05522	PROFEMUR® L Stem	Size 11



Profemur® L Revision Stems

PRFLKITB

Catalog No.	Description	Size
PHA05664	PROFEMUR® L Revision Stem	Size 5
PHA05666	PROFEMUR® L Revision Stem	Size 7
PHA05668	PROFEMUR® L Revision Stem	Size 9
PHA05670	PROFEMUR® L Revision Stem	Size 10
PHA05672	PROFEMUR® L Revision Stem	Size 11



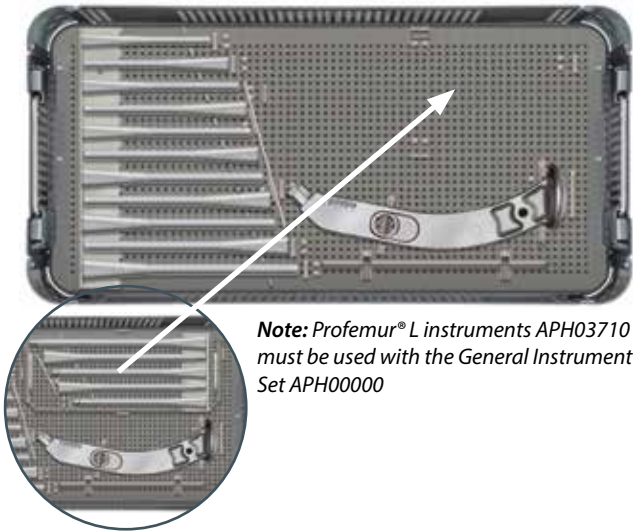
Profemur® Modular Necks COCRKITA

Catalog No.	Description
PHA01202	Straight Short (Ti alloy)
PHAC1204	Straight Long (CoCr alloy)
PHA01252	Varus / Valgus 8° Short (Ti alloy)
PHAC1254	Varus / Valgus 8° Long (CoCr 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	Ante / Retro - Varus /Valgus 2 Long (CoCr alloy)

Profemur® L Classic Stems PRFLKITD



Catalog No.	Description	Size
PHAS5502	Classic Standard	1
PHAS5504	Classic Standard	2
PHAS5506	Classic Standard	3
PHAS5508	Classic Standard	4
PHAS5510	Classic Standard	5
PHAS5512	Classic Standard	6
PHAS5514	Classic Standard	7
PHAS5516	Classic Standard	8
PHAS5518	Classic Standard	9
PHAS5520	Classic Standard	10
PHAS5522	Classic Standard	11
PHAE5502	Classic Extended	1
PHAE5504	Classic Extended	2
PHAE5506	Classic Extended	3
PHAE5508	Classic Extended	4
PHAE5510	Classic Extended	5
PHAE5512	Classic Extended	6
PHAE5514	Classic Extended	7
PHAE5516	Classic Extended	8
PHAE5518	Classic Extended	9
PHAE5520	Classic Extended	10
PHAE5522	Classic Extended	11



Note: Profemur® L instruments APH03710 must be used with the General Instrument Set APH00000

APH03703

Note: APH03703 consists of Profemur® L primary stem instruments (APH03710) and revision rasps with inner tray.

Note: To implant the Profemur® L Classic option, the following trial necks and templates must be ordered separately: (APA11170, APA11172 and CRL1CL03E)

Profemur® L Instruments
APH03710

Catalog No.	Description
APA07502	Profemur® L Broach Size 1
APA07504	Profemur® L Broach Size 2
APA07506	Profemur® L Broach Size 3
APA07508	Profemur® L Broach Size 4
APA07510	Profemur® L Broach Size 5
APA07512	Profemur® L Broach Size 6
APA07514	Profemur® L Broach Size 7
APA07516	Profemur® L Broach Size 8
APA07518	Profemur® L Broach Size 9
APA07520	Profemur® L Broach Size 10
APA07522	Profemur® L Broach Size 11
CRL1CL01E	Profemur® L X-Ray Templates
PRL0TR01	Profemur® L Tray 1
PPW38078	Rasp Handle Profemur® (Optional)
APA00006	Tommy Bar (Optional)
130561/150802	PKG Insert Instrument Cleaning

Profemur® L Revision Instruments
APH03701



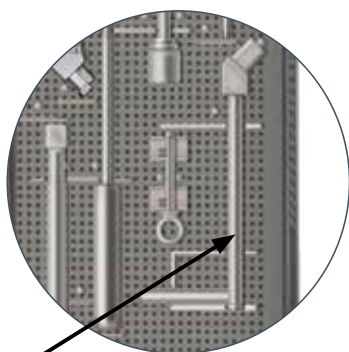
NOTE: Profemur® L Revision instruments APH03701 must be used with the General Instrument Set APH00000

NOTE: APH03703 consists of Profemur® primary stem instruments (APH03710) and revision rasps with inner tray (see picture page 17).

Catalog No.	Description
APA07564	Profemur® L Revision Rasp Size 5
APA07566	Profemur® L Revision Rasp Size 7
APA07568	Profemur® L Revision Rasp Size 9
APA07570	Profemur® L Revision Rasp Size 10
APA07572	Profemur® L Revision Rasp Size 11
PRL0TR02	Profemur® L Revision Tray 2
CRL1CL02E	Profemur® L Revision X-Ray Templates
130561/150802	PKG Insert Instrument Cleaning

General Instrument Kit

APH00000



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 8°
APA11134	Profemur® Trial Neck Long A/R 8°
APA11142	Profemur® Trial Neck Short A/R 15°
APA11144	Profemur® Trial Neck Long A/R 15°
APA11152	Profemur® Trial Neck Short VAR/VAL 8°
APA11154	Profemur® Trial Neck Long VAR/VAL 8°
APA11162	Profemur® Trial Neck Short VAR/VAL 15°
APA11164	Profemur® Trial Neck Long VAR/VAL 15°
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 Impacto <i>(Optional)</i>
PPX028960	Oriantator Handle <i>(Optional)</i>
130561/150802	Package Insert Instrument Cleaning

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

Chapter 7

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 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:
 - o 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 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.

™Trademarks and *Registered marks of MicroPort Orthopedics.
©2015 MicroPort Orthopedics. All Rights Reserved.

010485A_Jan15