Profemur® Renaissance®

Hip System: Classic Stems

Surgical Technique

MicroPort Orthopedics

Full Function, Faster®

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

Chapter 1

Design Rationale

The Profemur® Renaissance® Hip System is a "ream and broach" stem design that provides immediate stability through fixation of the diaphyseal canal. Reamers prepare the canal diameter to size, and press-fit distal splines provide rotational stability once the stem is implanted. The stem has two medial flare options designed to optimize fit, stability, and load transfer based on the patient anatomy: "standard flare" for femurs with moderate cortical wall thickness, and "reduced flare" for femurs with thick cortical walls ("champagne flute" canals). Secondary fixation is achieved via titanium plasma spray coating to promote bone ingrowth.

The Profemur® Renaissance® Hip system has 16 stem sizes to optimize fit for each patient anatomy. Replicating leg length and neck offset is achieved in the Profemur® Renaissance® Classic stem with a combination of short/long and straight/varus necks.

Chapter 2

Product Information

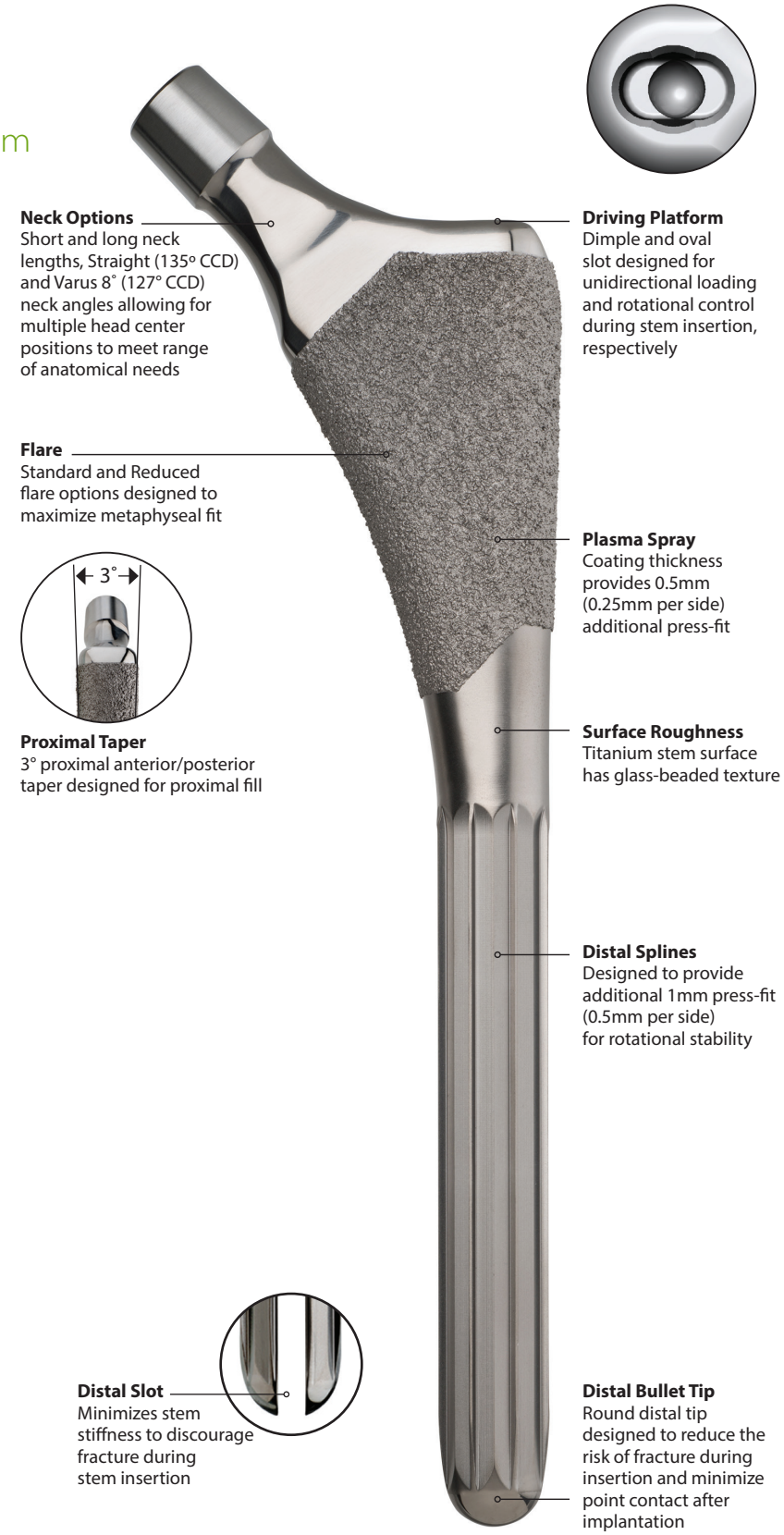
Profemur® Renaissance® Classic Stem Design Features

Abbreviated Technique: Ream and Broach
Ream to templated size or cortical chatter
Sequentially broach with reduced flare broaches to corresponding reamer size
If it is not secure, switch to standard flare broach or ream and broach to larger stem size
Implant size and flare corresponding to broach size and flare

Ordering Information	
Templates	PRNCXR15 (Short Neck Classic) PRNLXR15 (Long Neck Classic)
Surgical Technique	008118
Instruments	PRGIKIT1 (Includes trial necks) PRZNKIT1 (Broaches and broach handles) PRZNKIT2 (Reamers) PRCLIMPT (Classic stem impactor)
Implants	PRRCKITS (Short neck stems) PRRCKITL (Long neck stems)

Sizes	
Neck	Short and Long
Reduced Flare	10 - 16
Standard Flare	10 - 18

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



Profemur® Renaissance® Stems - General Specifications

General Specifications

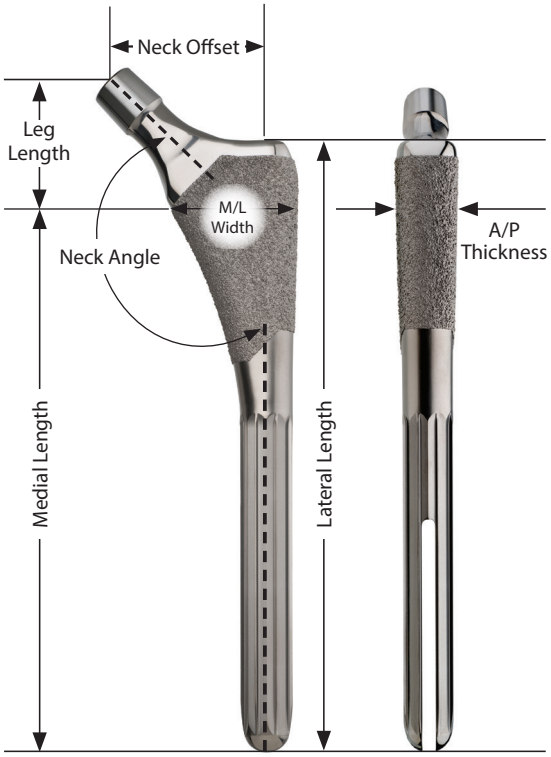
- Stems are made of titanium alloy
- Commercially-pure titanium plasma spray over proximal region (0.5mm/side)
- Medial Stem Length: 125 - 170mm
- M/L Width: 27 – 40mm
- Distal splines are 1mm larger than matching reamer
- A/P Thickness: 14 – 17mm

Profemur® Renaissance® Hip Stems Dimensional Chart

(Measurements in millimeters)

		Short Neck		Long Neck		Stem Measurements			
	Size	Leg Length	Neck Offset	Leg Length	Neck Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
	Straight (Neck Angle = 135°)								
Reduced	10	31	33	38	41	125	28	14	145
Reduced	11	31	35	38	42	129	28	15	148
Reduced	12	31	36	39	44	134	30	16	154
Reduced	13	32	37	40	45	140	31	17	158
Reduced	14	32	37	40	45	145	32	18	163
Reduced	15	33	39	41	47	150	33	19	170
Reduced	16	33	39	41	47	154	34	21	175
Standard	10	31	33	38	41	125	30	14	145
Standard	11	31	35	38	42	129	30	15	148
Standard	12	31	36	39	44	134	32	16	154
Standard	13	32	37	40	45	140	33	17	158
Standard	14	32	37	40	45	145	34	18	163
Standard	15	33	39	41	47	150	35	19	170
Standard	16	33	39	41	47	154	36	21	175
Standard	17	33	41	40	49	160	37	22	180
Standard	18	33	42	40	49	170	38	23	190
	Varus 8° (Neck Angle = 127°)								
Reduced	10	29	36	35	45	125	28	14	145
Reduced	11	27	38	35	46	129	28	15	148
Reduced	12	28	40	36	48	134	30	16	154
Reduced	13	28	41	37	49	140	31	17	158
Reduced	14	28	41	37	49	145	32	18	163
Reduced	15	30	43	38	51	150	33	19	170
Reduced	16	30	43	38	51	154	34	21	175
Standard	10	29	36	35	45	125	30	14	145
Standard	11	27	38	35	46	129	30	15	148
Standard	12	28	40	36	48	134	32	16	154
Standard	13	28	41	37	49	140	33	17	158
Standard	14	28	41	37	49	145	34	18	163
Standard	15	30	43	38	51	150	35	19	170
Standard	16	30	43	38	51	155	36	21	175
Standard	17	29	45	37	53	160	37	22	180
Standard	18	30	46	37	53	170	38	23	190

Offset and Leg Length are based on +0 head.



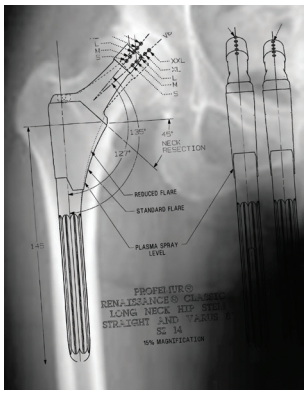
Head Center Adjustment Chart

(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 3

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.

The neck angle and head length which most closely correspond to the patient's femoral head center can be estimated as well. The ideal head will align atop the previously determined center of rotation for the femoral head. In patients with significant deformity of the femoral head, templating can be performed on the opposite hip if necessary.

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

Each circle represents the center of rotation for a modular short neck with the corresponding head option (Short to XX Long). Each square represents the center of rotation for a modular long neck with the corresponding head option (Short to XX Long). 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.

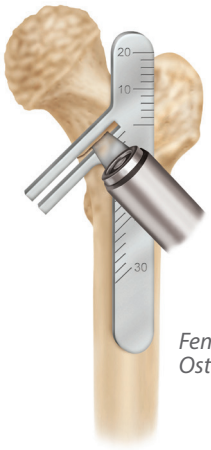
NOTE: AR/VV necks can also affect neck position by 6˚ varus/valgus.

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.

Chapter 4

Surgical Technique



Femoral Neck Osteotomy

Open the Femoral Canal

Femoral Neck Osteotomy

Using the greater trochanter or lesser trochanter as a reference, resect the neck at a 45° angle to the longitudinal axis of the femur. The Profemur® Neck Resection Guide (P/N PTRG0410) is available to help establish the angle of resection.

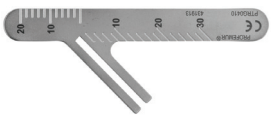
Open the Femoral Canal

Using the Profemur® Box Chisel (P/N PRFS0450), open the femoral canal. The box chisel should be lateralized to ensure a neutral orientation of the implant.

Starter Reamer

Enter the femoral canal with the Profemur® Initial Reamer (P/N APA04750). Proper reaming depth, measured from the medial resection, corresponds to stem length. Using the Profemur® Renaissance® Proximal Reamer (P/N PSSR1118), clear out the lateral greater trochanter to allow straight access to the femoral canal.

It is important to stay lateral with the box chisel, starter reamer, and proximal reamer. Care should be taken to ensure that the initial reaming track into the femur is in neutral alignment with the femoral axis.

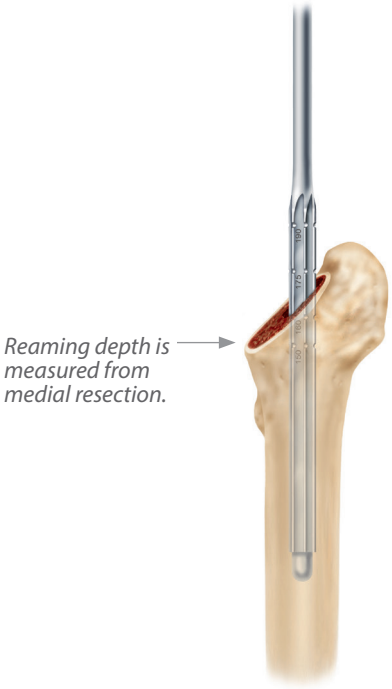


Profemur® Neck Resection Guide (P/N PTRG0410)

Profemur® Box Chisel P/N PRFS0450

Profemur®Initial Reamer P/N APA04750

Profemur®Renaissance® Proximal Reamer P/N PSSR1118



Femoral Reaming

Starting with the smallest reamer, Profemur® Femoral Reamer Size 8 (P/N PRR00080), sequentially ream the femoral canal to the appropriate depth and diameter based on the templated size and the amount of resistance that the reamer encounters.

Stem length is measured from the upper most plasma line on the medial side (resection line) to the distal tip of the implant. Proper reaming depth, measured off of the medial resection, corresponds to stem length.

Profemur® Renaissance® Reaming Chart

Stem Size	Reaming Depth
10	125mm
11	130mm
12	135mm
13	140mm
14	145mm
15	150mm
16	155mm
17-18	160mm

Profemur® Renaissance® Reamer Size 8
P/N PRR00080

Femoral Broaching

Prepare the femoral canal with the Profemur® Renaissance® Starter Broach (P/N PLRB0009). 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. Insert the broach until it rests 1-2mm below the level of the neck resection.

Attach the broach handle of choice (P/N SLBROHAN is shown) to the smallest reduced flare broach. Begin broaching using a mallet with short, controlled strokes. Sequentially broach to the appropriate size, using the reduced flare Profemur® Renaissance® Broaches (P/N PLRB0010-18).

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.

Continue broaching until an optimal fit is found. Once the appropriately sized broach is fully seated, leave the broach fully seated in the canal and detach the broach handle to allow for trial reduction.

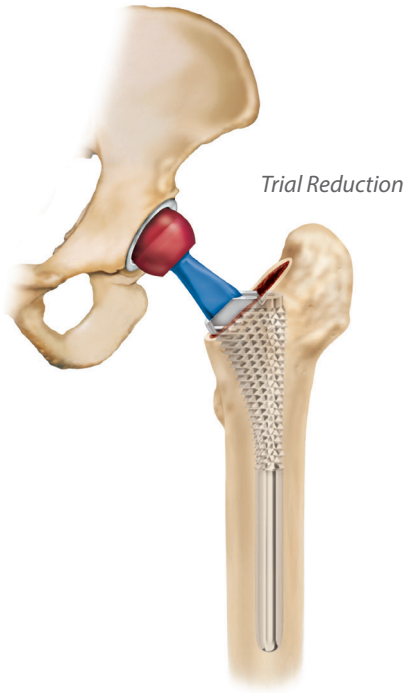
CAUTION: *The Profemur® Renaissance® hip system includes both standard and reduced flare broaches and implants. Broaching is performed sequentially, using the reduced flare broaches, to the equivalent reamer size used during the femoral reaming process. If the fit is not secure, sequentially broach to the equivalent reamer size using the standard flare Profemur® Renaissance® Broaches (P/Ns PLSB0010-18).*

NOTE: The femoral broaches are 0.5mm smaller than the plasma spray of the implant, providing 0.5mm (0.25mm per side) of press-fit proximally.

Profemur® Renaissance® Starter Broach
P/N PLRB0009

Profemur® Renaissance® Broach
P/N PLRB0010-18

Profemur® Slotted Broach Handle
P/N SLBROHAN



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.

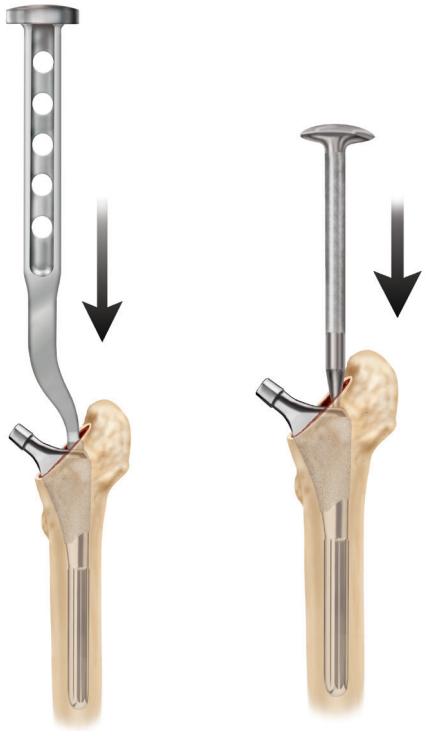
Trial Reduction

Select the appropriate plastic or metal Profemur® Trial Neck (P/Ns APA11102, APA11104, APA11152, APA11154 or APA12102, APA12104, APA12152, APA12154) and either the Profemur® Trial Head (P/Ns APA02121 - APA02154) or the Trial Head/Neck Sleeve combination (P/Ns 41103600 41104800 and P/Ns APA0TSS3, APA0TSM0, APA0TSL3 or APA0TSX7) and perform a trial reduction. Metal Profemur® Trial Necks are equivalent dimensionally to the plastic Profemur® Trial Necks. Once a well balanced hip has been created with a trial head and trial neck, remove the broach.

Summary of Profemur® Renaissance® 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.

Use the Profemur® Classic Stem Inserter (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 a unidirectonal load. Fully seat the implant using short, controlled strokes with a surgical mallet. Typically, the final implant is seated with the base of the polished neck at the neck resection cut.

Final Trial Reduction

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

Head Assembly

Ensure the stem taper is clean and dry prior to assembly, and then affix the femoral head to the neck. Using the head impactor instrument, strike the impactor with **three very firm blows** with a mallet to securely fix the head to the stem.

NOTE: Place a femoral head impactor (such as P/N 4400F10000 or PPR67200) on a ceramic femoral head, and align the impactor with the femoral neck axis of the stem implant. With a moderate top of the hammer in the axial direction, firmly impact the ceramic femoral head on the stem taper until it is fully seated.

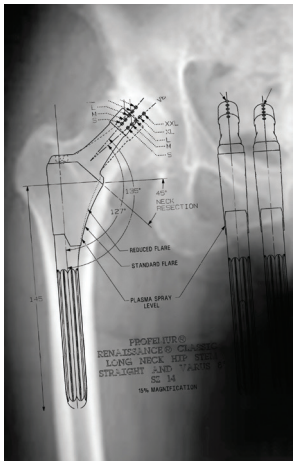
Position the leg such that the knee is supported by an assistant on the opposite side of the table. By resting the patient's knee against the mid-section of the assistant, this will provide counter-force against the mallet blows to ensure the impaction load transfer to the neck junction.

Profemur® Classic Stem Inserter
P/N PRCLIMPT

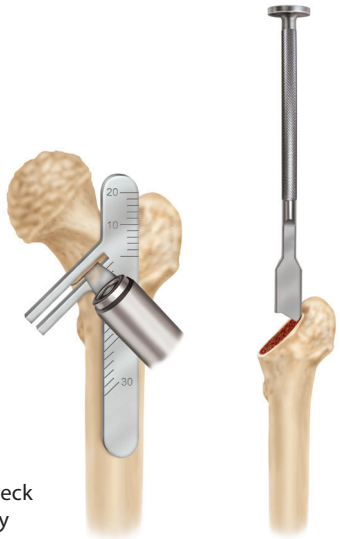
Final Stem Impactor
P/N PPF60200

Chapter 5

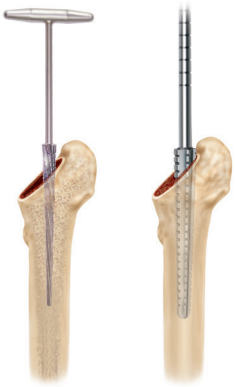
Technique Overview



1. X-ray

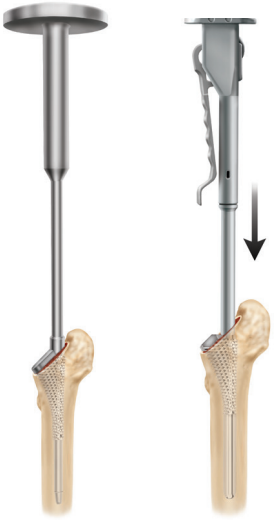


2. Femoral Neck Osteotomy

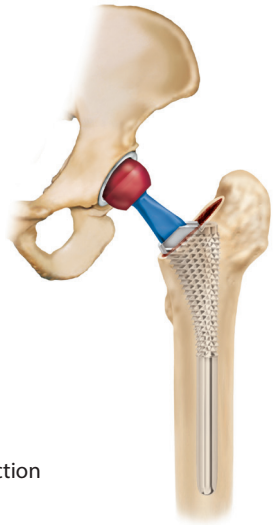


3. Femoral Canal Preparation

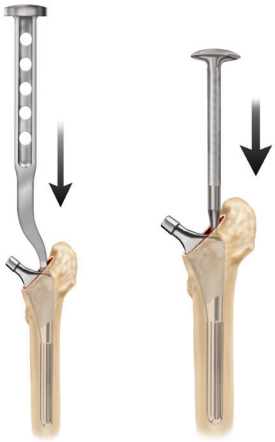
4. Femoral Reaming



5. Femoral Broaching



6. Trial Reduction



7. Stem Insertion

8. Implant Assembly

Chapter 6

Implant Removal

Profemur® Renaissance® Classic Stem Removal

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

Classic Stem Removal

Should the removal of a Profemur® Classic stem become necessary, the 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.

NOTE: Classic stem extraction instruments must be ordered separately.

Universal Stem Extractor
P/N 4700SE05

Slap Hammer
P/N 4700SH0000

Chapter 6

Ordering Information

Profemur® Renaissance® Classic Stems - Short Necks

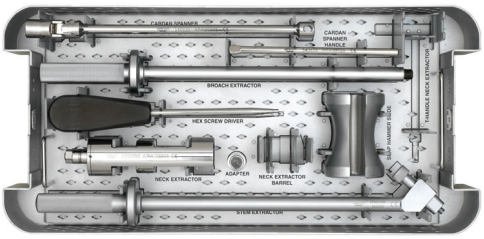
PRRCKITS

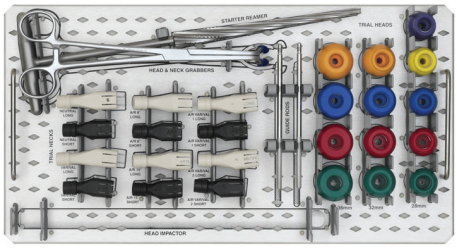
Catalog No.	Flare	Neck Angle	Size
PLSES010	Standard	Varus 8˚	10
PLSES011	Standard	Varus 8˚	11
PLSES012	Standard	Varus 8˚	12
PLSES013	Standard	Varus 8˚	13
PLSES014	Standard	Varus 8˚	14
PLSES015	Standard	Varus 8˚	15
PLSES016	Standard	Varus 8˚	16
PLSES017	Standard	Varus 8˚	17
PLSES018	Standard	Varus 8˚	18
PLSSS010	Standard	Straight	10
PLSSS011	Standard	Straight	11
PLSSS012	Standard	Straight	12
PLSSS013	Standard	Straight	13
PLSSS014	Standard	Straight	14
PLSSS015	Standard	Straight	15
PLSSS016	Standard	Straight	16
PLSSS017	Standard	Straight	17
PLSSS018	Standard	Straight	18
PLSER010	Reduced	Varus 8˚	10
PLSER011	Reduced	Varus 8˚	11
PLSER012	Reduced	Varus 8˚	12
PLSER013	Reduced	Varus 8˚	13
PLSER014	Reduced	Varus 8˚	14
PLSER015	Reduced	Varus 8˚	15
PLSER016	Reduced	Varus 8˚	16
PLSSR010	Reduced	Straight	10
PLSSR011	Reduced	Straight	11
PLSSR012	Reduced	Straight	12
PLSSR013	Reduced	Straight	13
PLSSR014	Reduced	Straight	14
PLSSR015	Reduced	Straight	15
PLSSR016	Reduced	Straight	16

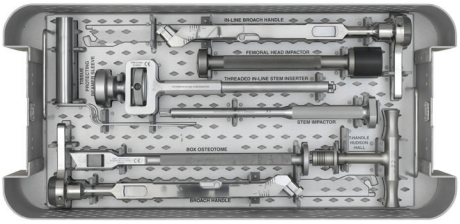
Profemur® Renaissance® Classic Stems - Long Necks

PRRCKITL

Catalog No.	Flare	Neck Angle	Size
PLLES010	Standard	Varus 8˚	10
PLLES011	Standard	Varus 8˚	11
PLLES012	Standard	Varus 8˚	12
PLLES013	Standard	Varus 8˚	13
PLLES014	Standard	Varus 8˚	14
PLLES015	Standard	Varus 8˚	15
PLLES016	Standard	Varus 8˚	16
PLLES017	Standard	Varus 8˚	17
PLLES018	Standard	Varus 8˚	18
PLLSS010	Standard	Straight	10
PLLSS011	Standard	Straight	11
PLLSS012	Standard	Straight	12
PLLSS013	Standard	Straight	13
PLLSS014	Standard	Straight	14
PLLSS015	Standard	Straight	15
PLLSS016	Standard	Straight	16
PLLSS017	Standard	Straight	17
PLLSS018	Standard	Straight	18
PLLER010	Reduced	Varus 8˚	10
PLLER011	Reduced	Varus 8˚	11
PLLER012	Reduced	Varus 8˚	12
PLLER013	Reduced	Varus 8˚	13
PLLER014	Reduced	Varus 8˚	14
PLLER015	Reduced	Varus 8˚	15
PLLER016	Reduced	Varus 8˚	16
PLLSR010	Reduced	Straight	10
PLLSR011	Reduced	Straight	11
PLLSR012	Reduced	Straight	12
PLLSR013	Reduced	Straight	13
PLLSR014	Reduced	Straight	14
PLLSR015	Reduced	Straight	15
PLLSR016	Reduced	Straight	16



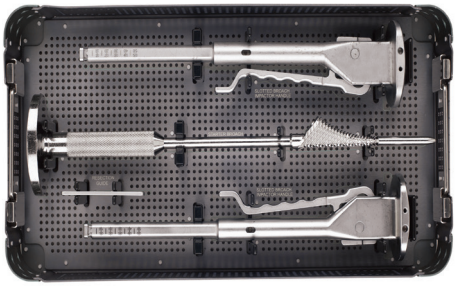




Profemur® Standard Instrument Kit

PRGIKIT1

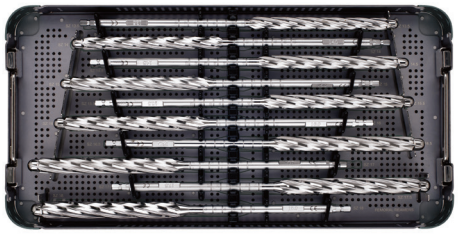
Catalog No.	Description
20070050	Modular Neck Inserter
4400FI0000	Femoral Head Impactor
APA00001	Head/Neck Extractor
APA00003	Head/Neck Extractor Adaptor 12/14
APA00005	Head/Neck Extractor Cardan Spanner Hex
APA00006	Head/Neck Extractor Tommy Bar
APA02121	Femoral Trial Head 28mm Short (-3.5mm)
APA02122	Femoral Trial Head 28mm Medium (+0mm)
APA02123	Femoral Trial Head 28mm Long (+3.5mm)
APA02124	Femoral Trial Head 28mm XLong (+7mm)
APA02125	Femoral Trial Head 28mm XXLong (+10.5mm)
APA02142	Femoral Trial Head 36mm Short (-3.5mm)
APA02144	Femoral Trial Head 36mm Medium (+0mm)
APA02146	Femoral Trial Head 36mm Long (+3.5mm)
APA02148	Femoral Trial Head 36mm XLong (+7mm)
APA02151	Femoral Trial Head 32mm Short (-3.5mm)
APA02152	Femoral Trial Head 32mm Medium (+0mm)
APA02153	Femoral Trial Head 32mm Long (+3.5mm)
APA02154	Femoral Trial Head 32mm XLong (+7mm)
APA04241	Profemur® MIS Broach Handle (Qty 2)
APA04244	Broach Handle Alignment Guide Rod (Qty 2)
APA04750	Profemur® Starter Reamer
APA11102	Profemur® Short Straight Plastic Trial Neck
APA11104	Profemur® Long Straight Plastic Trial Neck
APA11112	Profemur® Short A/R Var/Val 1 Plastic Trial Neck
APA11114	Profemur® Long A/R Var/Val 1 Plastic Trial Neck
APA11122	Profemur® Short A/R Var/Val 2 Plastic Trial Neck
APA11124	Profemur® Long A/R Var/Val 2 Plastic Trial Neck
APA11132	Profemur® Short A/R 8° Plastic Trial Neck
APA11134	Profemur® Long A/R 8° Plastic Trial Neck
APA11142	Profemur® Short A/R 15° Plastic Trial Neck
APA11144	Profemur® Long A/R 15° Plastic Trial Neck
APA11152	Profemur® Short Var/Val 8° Plastic Trial Neck
APA11154	Profemur® Long Var/Val 8° Plastic Trial Neck
K0001016	Quick Disconnect T-Handle
PP275400	Hex Screwdriver
PPR67688	Slap Hammer Stem Extractor
PRFS0450	Profemur® Box Chisel
PRFS0460	Profemur® Screwdriver Inserter
PRFS0462	Profemur® Broach Extraction Shaft
PRFS0463	Profemur® Tissue Protecting Sleeve
PRFS1461	Profemur® Threaded In-Line Stem Inserter

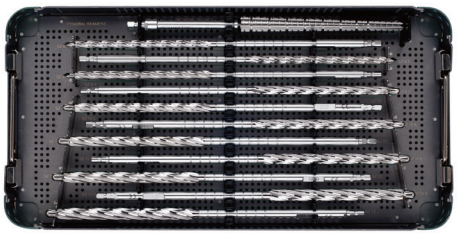


Instruments

PRZNKIT1

Catalog No.	Description
PLRB0009	Profemur® Renaissance® Starter Broach
PLSB0010	Profemur® Renaissance® Broach Standard 10
PLSB0011	Profemur® Renaissance® Broach Standard 11
PLSB0012	Profemur® Renaissance® Broach Standard 12
PLSB0013	Profemur® Renaissance® Broach Standard 13
PLSB0014	Profemur® Renaissance® Broach Standard 14
PLSB0015	Profemur® Renaissance® Broach Standard 15
PLSB0016	Profemur® Renaissance® Broach Standard 16
PLSB0017	Profemur® Renaissance® Broach Standard 17
PLSB0018	Profemur® Renaissance® Broach Standard 18
PLRB0010	Profemur® Renaissance® Broach Reduced 10
PLRB0011	Profemur® Renaissance® Broach Reduced 11
PLRB0012	Profemur® Renaissance® Broach Reduced 12
PLRB0013	Profemur® Renaissance® Broach Reduced 13
PLRB0014	Profemur® Renaissance® Broach Reduced 14
PLRB0015	Profemur® Renaissance® Broach Reduced 15
PLRB0016	Profemur® Renaissance® Broach Reduced 16
PLRB0017	Profemur® Renaissance® Broach Reduced 17
PLRB0018	Profemur® Renaissance® Broach Reduced 18
PTRG0410	Profemur® Renaissance® Neck Resection Guide
PLRB0016	Profemur® Slotted Broach Impactor Handle (Qty 2)





Instruments

PRZNKIT2

Catalog No.	Description
PSSR1118	Profemur® Renaissance® Proximal Reamer
PRR00080	Profemur® Femoral Reamer 8
PRR00085	Profemur® Femoral Reamer 8.5
PRR00090	Profemur® Femoral Reamer 9
PRR00095	Profemur® Femoral Reamer 9.5
PRR00100	Profemur® Femoral Reamer 10
PRR00105	Profemur® Femoral Reamer 10.5
PRR00110	Profemur® Femoral Reamer 11
PRR00115	Profemur® Femoral Reamer 11.5
PRR00120	Profemur® Femoral Reamer 12
PRR00125	Profemur® Femoral Reamer 12.5
PRR00130	Profemur® Femoral Reamer 13
PRR00135	Profemur® Femoral Reamer 13.5
PRR00140	Profemur® Femoral Reamer 14
PRR00145	Profemur® Femoral Reamer 14.5
PRR00150	Profemur® Femoral Reamer 15
PRR00155	Profemur® Femoral Reamer 15.5
PRR00160	Profemur® Femoral Reamer 16
PRR00165	Profemur® Femoral Reamer 16.5
PRR00170	Profemur® Femoral Reamer 17
PRR00175	Profemur® Femoral Reamer 17.5
PRR00180	Profemur® Femoral Reamer 18

Stem Impactors

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

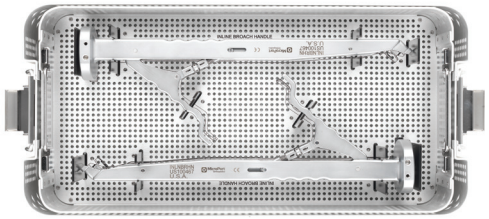
Woodpecker Broaching System

4251KT10

Catalog No.	Description
APA00930	Woodpecker
APA00931	Hose Attachment
APA00943	Broach Handle

Profemur® Renaissance® X-Ray Templates

Catalog No.	Description
PRNCXR15	Profemur® Renaissance® Classic Short Neck X-Ray Template 15% Magnification
PRNLXR15	Profemur® Renaissance® Classic Long Neck X-Ray Template 15% Magnification



Broach Handle

SPBHKIT1

Catalog No.	Description
INLNBRHN	Inline Broach Handle (Qty 2)

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

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

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

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

Other Modular Components (Femoral Heads, Neck Trunnions)
Scratching of femoral heads and neck trunnions should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Ensure components are firmly seated to prevent disassociation. The femoral head and neck trunnion **must** be clean and dry before assembly. 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. The modular femoral head should be changed only when necessary.

The neck/body component or neck/femoral stem should be changed only when clinically necessary.

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

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

MicroPort Orthopedics

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.