Profemur® Z

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

Design Rationale

The Profemur® Z hip system combines Zweymüller-style hip stems with the flexibility of MicroPort's patented modular neck technology. The geometry of these titanium-alloy implants include a dual-tapered wedge designed to provide proximal fixation and rotational stability in a primary and a revision length stem. The cementless primary stems are provided with grit-blast and plasma-coated surfaces, while the cementless revision stems are provided with a grit-blast surface only. In addition, the primary stems are provided in a fixed-neck (Classic) option for use when the anatomy of the patient is standard in nature, and modular neck options for use when the patient anatomy suggests a varied orientation. Adding such modularity allows the surgeon to customize the reconstruction to assist in replicating the anatomy[1] and provide intra-operative versatility to address soft tissue tension[2] as needed. The modular neck system allows easy changes to offset and simultaneous adjustment of version regardless of the length of the neck.[1]

Stems

Profemur® Plasma Z Classic
Primary fixed-neck stem with proximal plasma coating over grit-blast surface

Profemur® Z Classic
Primary fixed-neck stem with grit-blast surface

Profemur® Plasma Z
Primary modular stem with proximal plasma coating over grit-blast surface

Profemur® Z
Primary modular stem with grit-blast surface

Profemur® Z Revision
Revision modular stem with grit-blast surface

Features

- Dual-tapered wedge design
- Heavy grit-blast surface
- Commercially-pure titanium plasma coating
- Modular and monolithic stem options

[1]Omlor, Georg W, Hannah Ullrich, Knut Krahmer, Alexander Jung, Gunther Aldinger, and Peter Aldinger. "Summary: A stature-specific concept for uncemented, primary total hip arthroplasty 10-year results in 155 patients using two stem shapes and modular necks". Acta Orthopaedica 81 (1) Feb. 2010

[2]Traina, Francesco, Manuela De Clerico, Federico Biondi, Federico Pilla, Enrico Tassinari and Aldo Toni. "Sex Differences in Hip Morphology: Is Stem Modularity Effective for Total Hip Replacement?" JBJS (91) Suppl. 6, Nov. 2009

Chapter 2

Product Information

Profemur® Z Classic and Plasma Z Classic Stems Design Features

Abbreviated Technique: Broach-only
Broach to templated size
Implant size corresponding to broach size

Ordering Information	
Templates	PRFNXR15 (Long Neck Classic)
	PRZCXR15 (Short Neck Classic)
Surgical Technique	010911
Instruments	4251KIT1 (Core instruments, plastic trial necks, broach handles) PRZSKIT2 (Slotted broach handles and broaches) APA04750 (Starter reamer)
Implants	PHAZKITA (Long Neck Classic) PHAPKITA (Long Neck Plasma Classic) PZCLKITA (Short Neck Classic) PPZCKITA (Short Neck Plasma Classic)

Sizes	
Neck	Short and Long
Stem	1 - 9

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

Driving Platform
Short and long neck stems have dimple designed for unidirectional loading. Short neck stems have an additional oval feature to provide rotational control.

Trochanteric Wing
Increased trochanteric wing designed to contribute to proximal fill and rotational stability

Dual Taper Geometry
Design intended to provide optimal primary fixation and load transfer

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

Profemur® Z and Plasma Z Stems Design Features

Abbreviated Technique: Broach-only
Broach to templated size
Implant size corresponding to broach size

Ordering Information	
Templates	PRFZXR15
Surgical Technique	010911
Instruments	4251KIT1 (Core instruments, plastic trial necks, broach handles) PRZSKIT2 (Slotted broach handles and broaches) APA04750 (Starter reamer)
Implants	4251KITA (Z) 4251KITB (Plasma Z) COCRKITB (Cobalt chrome modular necks)

Sizes	
Stem	1 - 9

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

Driving Platform
Dimple designed for unidirectional loading during stem insertion

Trochanteric Wing
Increased trochanteric wing designed to contribute to proximal fill and rotational stability

Plasma Spray
Coating thickness of 1mm (0.5mm per side) for additional press-fit

Dual Taper Geometry
Design intended to provide primary fixation and load transfer

Rectangular Cross-Section
Provides rotational stability and conserves bone for increased vascularization

Surface Roughness
Titanium stem surface has heavy grit-blast texture

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

Profemur® Z Revision Stem Design Features

Abbreviated Technique: Broach-only
Broach to templated size
Implant size corresponding to broach size

Ordering Information	
Templates	PRZRXR15
Surgical Technique	010911
Instruments	PRZRKIT1 (Broaches) SPBHKIT1 (In-line broach handle) PRGIKIT1 (Includes plastic trial heads, broach handles)
Implants	PRZRKITA (Revision Z) COCRKITB (Cobalt chrome modular necks)

Sizes	
Stem	3 - 11 (40mm longer than corresponding primary size)

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

Driving Platform
Dimple designed for unidirectional loading during stem insertion

Trochanteric Wing
Increased trochanteric wing designed to contribute to proximal fill and rotational stability

Rectangular Cross-Section
Provides rotational stability and conserves bone for increased vascularization

Dual Taper Geometry
Design intended to provide optimal primary fixation and load transfer

Surface Roughness
Titanium stem surface has heavy grit-blast texture

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

Profemur® Z and Z Revision Stems - General Specifications

Profemur® Z Stem

- M/L Length: 110 - 139mm
- M/L Width: 32 – 40mm
- A/P Thickness: 14 – 16mm

Profemur® Z Revision Stem

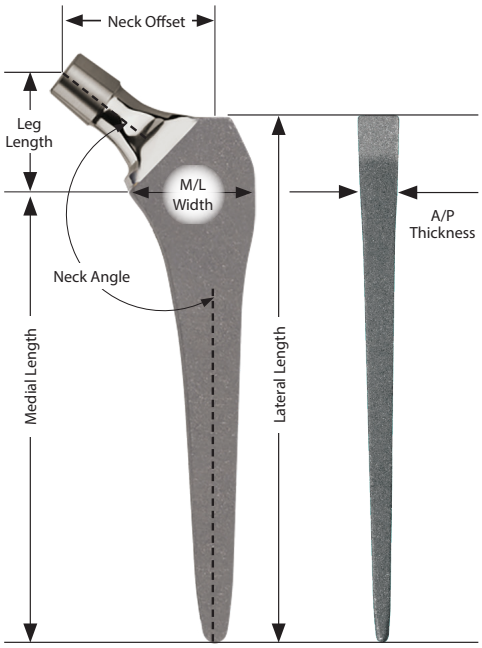
- M/L Length: 158 - 186mm
- M/L Width: 33 – 43mm
- A/P Thickness: 13 – 16mm

Profemur® Z Plasma & Grit-Blasted Primary Hip Stems Dimensional Chart

(Measurements in millimeters)

	Short Neck Classic and Modular		Long Neck Classic and Modular		Stem Measurements			
Size	Neck Length	Offset	Neck Length	Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
Straight (Neck Angle = 135°)								
1	26	30	34	38	110	32	14	126
2	26	30	34	38	114	32	14	131
3	28	31	36	39	118	33	14	136
4	29	32	37	40	121	35	15	141
5	31	33	39	42	125	36	15	146
6	32	34	40	43	128	37	15	151
7	34	35	42	44	132	38	16	156
8	35	37	43	45	136	39	16	161
9	37	38	45	46	139	40	16	166
Varus 8° (Neck Angle = 127°)								
1	24	33	31	42	110	32	14	126
2	24	33	31	42	114	32	14	131
3	25	34	32	43	118	33	14	136
4	27	35	34	44	121	35	15	141
5	28	36	35	46	125	36	15	146
6	30	37	37	47	128	37	15	151
7	31	38	38	48	132	38	16	156
8	33	40	40	49	136	39	16	161
9	34	41	42	50	139	40	16	166

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



Profemur® Z Revision Hip Stems Dimensional Chart

(Measurements in millimeters)

	Short Neck Modular		Long Neck Modular		Stem Measurements			
Size	Neck Length	Offset	Neck Length	Offset	Med. Length	M/L Width	A/P Thick.	Lat. Length
Straight (Neck Angle = 135°)								
3	26	30	34	37	158	33	13	176
4	28	31	35	38	161	34	14	181
5	29	32	36	39	165	35	14	186
6	30	32	37	39	168	36	14	191
7	31	33	38	40	172	37	15	196
8	32	33	39	41	175	38	15	201
9	33	34	40	41	179	40	16	206
10	34	34	41	42	182	41	16	211
11	35	35	42	42	186	43	16	216
Varus 8° (Neck Angle = 127°)								
3	24	32	30	40	158	33	13	176
4	26	34	32	42	161	34	14	181
5	27	34	33	43	165	35	14	186
6	28	35	34	43	168	36	14	191
7	29	36	35	44	172	37	15	196
8	30	36	36	44	175	38	15	201
9	31	37	37	45	179	40	16	206
10	32	37	38	45	182	41	16	211
11	33	38	39	46	186	43	16	216

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

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

Profemur® Modular Necks Design Features

- Cobalt Chrome Material
- Varus Neck Angle: 127°
- Neutral Neck Angle: 135°
- Valgus Neck Angle: 143°

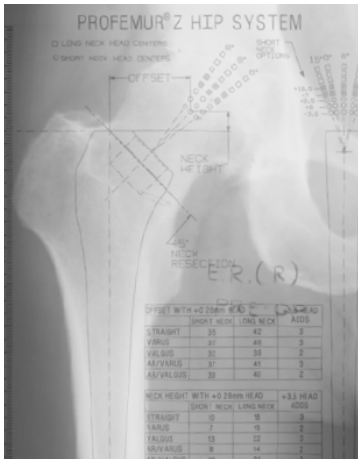
4°/8°/15° Anteversion
or Retroversion

6°/8° Varus or Valgus

Type	Length Options
Neutral	Short Long
Varus/Valgus	Short
Ante/Retro 8 Degree	Short Long
Ante/Retro 15 Degree	Short Long
Ante/Retro - Varus/Valgus 1	Short Long
Ante/Retro - Varus/Valgus 2	Short Long

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. 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 A/P 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

NOTE: Regarding the Profemur® Z Revision stem, steps 1 - 3 are not necessary unless using the stem in a primary THA.

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

Open the femoral canal using the Profemur® Starter Reamer (P/N APA04750, not included in kit 4251KIT1). The lateral side of the canal in the greater trochanter region should be cleared to allow straight access to the femoral canal. Manual reaming of the femur using this T-handle design is recommended to avoid over-reaming the canal, to maintain alignment control, and to minimize the amount of heat generated.

NOTE: If performing a THR using the Profemur® Z Revision stem, the original prosthesis and any remaining cement or other debris must be completely removed from the femoral canal.

Starter Broach (Optional)

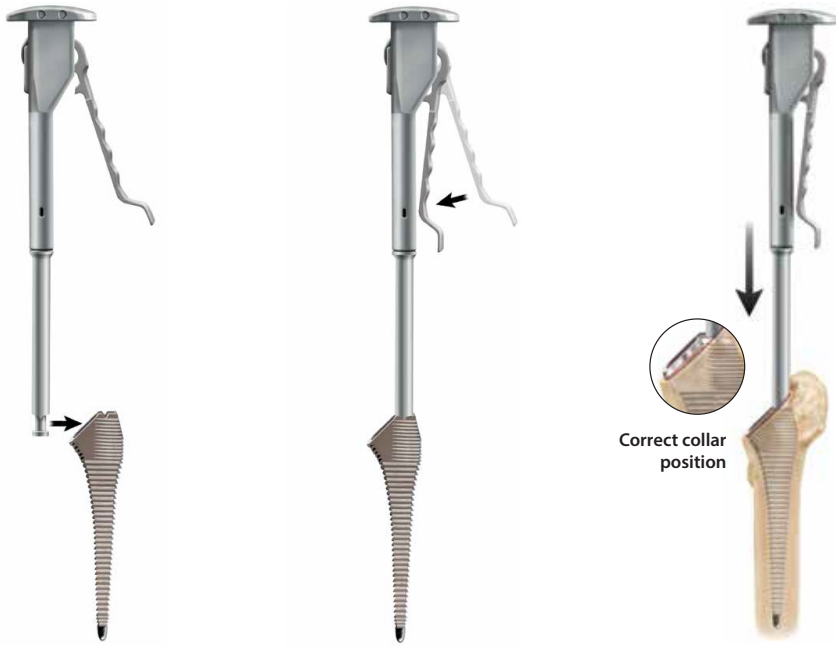
Prepare the femoral canal with the Profemur® Z Starter Broach (P/N APA01070). Staying centered between the anterior and posterior cortices, impact the starter broach until the top of the teeth rests just at or below the level of the neck resection.

Profemur® Neck Resection Guide
P/N PTRG0410

Profemur® Box Chisel
P/N PRFS0450

Profemur® Starter Reamer
P/N APA04750

Profemur® Z Starter Broach
P/N APA01070



Femoral Broaching

Attach the preferred broach handle (the Profemur® Slotted Broach Handle, P/N SLBROHAN, is shown) to the Size 1 Profemur® Z Slotted Broach (P/N APA08001). Using a mallet with short, controlled strokes, begin broaching.

Continue broaching by increasing the broach size incrementally until an optimal fit is found.

The top of the broach teeth is equal to the top of the plasma and grit-blast surface.

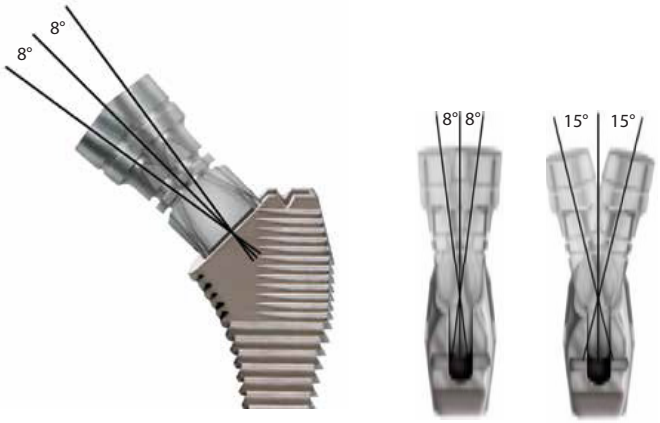
Sequentially increase the broach sizes while broaching until an optimal fit is found. This will be denoted by a change in tone or resistance as the rounded corners of the broach contact the cortical bone of the femur. To verify a secure fit, attempt to rotate the broach relative to the femur. With proper 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. If the surgeon desires, an intraoperative control radiograph can be obtained to confirm correct sizing.

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.

Slotted Broach Handle
P/N SLBROHAN

Profemur® Z Slotted Broach Size 1
P/N APA08001



Trial Reduction

Select the appropriate plastic or metal Profemur® Trial Neck (P/Ns APA11102 - APA11154 or APA12102 - 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 (P/Ns APA12102 - APA12154) 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.

For Classic stems, use only the short and long, straight and varus plastic and metal Profemur® Trial Necks (P/Ns APA11102, APA11104, APA11152, APA11154 or APA12102, APA12104, APA12152, APA12154) as they represent the Classic stem offerings.

Brief Summary of Neck Options for Profemur® Z Modular:

»» 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˚.

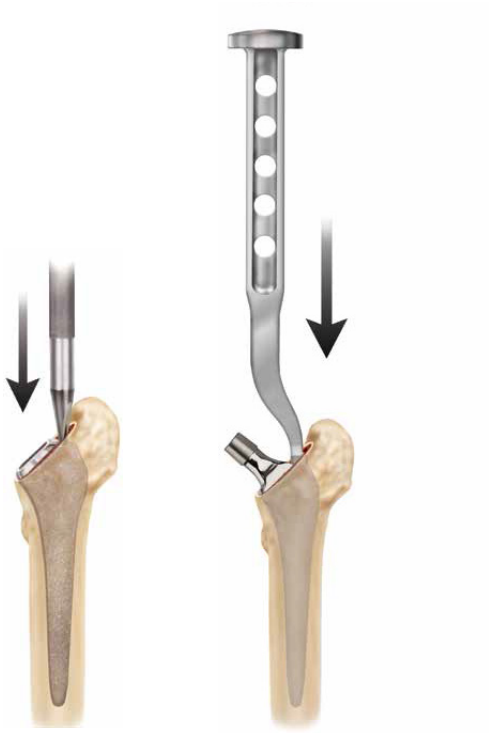
»» Retroverted necks shift the femoral head posteriorly relative to the stem by 8˚ or 15˚. Retroverted necks prove useful in hips with excess femoral anteversion such as DDH.

»» 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.

Brief Summary of Profemur® Z Classic Short Neck 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. Place the Final Stem Impactor (P/N PPF60200) into the dimple on the proximal face and, with a mallet, fully seat the implant using short, controlled strokes. For the Short Neck Classic stems, the Profemur® Classic Stem Inserter (P/N PRCLIMPT, not included in 4251KIT1) is also available to provide rotational control during impaction. Place the tip of the chosen impactor into the impaction feature on the proximal face 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.

For the Profemur® Plasma Z versions, the implant may sit 1-2mm prouder 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 head and neck combination.

Final Trial Reduction

Perform a final reduction using the trial heads (and trial necks for modular implants) to reconfirm stability, range of motion and leg length.

CAUTION: Do not use metal trial necks with a modular implant. Metal trial necks are only to be used with broaches since the may damage the neck taper. Only plastic trial necks (available in 4251KIT1) should be used for trial reductions with a modular implant.

Final Stem Impactor
P/N PPF60200

Stem Inserter
P/N PRCLIMPT

Implant Assembly

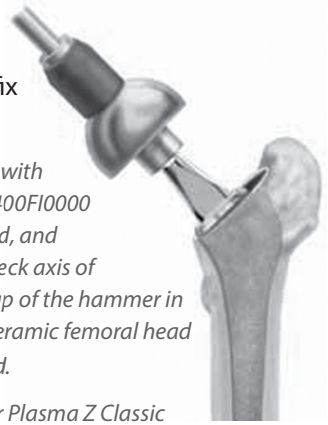
To properly assemble and impact a Profemur® modular neck, the following procedure is recommended:

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. 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 neck and stem.

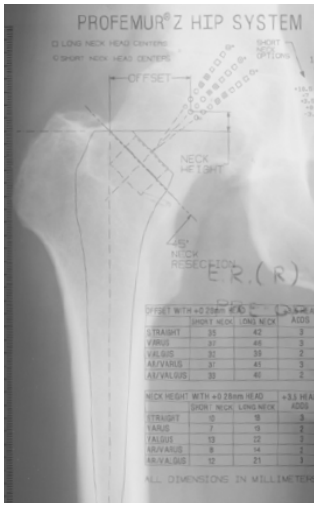


NOTE: Place a femoral head impactor with a plastic impaction tip (such as P/N 4400FI0000 or PPR67702) on ceramic femoral head, and align the impactor with the femoral neck axis of the stem implant. With a moderate tap of the hammer in an axial direction, firmly impact the ceramic femoral head on the stem taper until it is fully seated.

NOTE: If using a Profemur® Z Classic or Plasma Z Classic stem, affix the femoral head to the stem and impact as instructed.

Chapter 5

Technique Overview



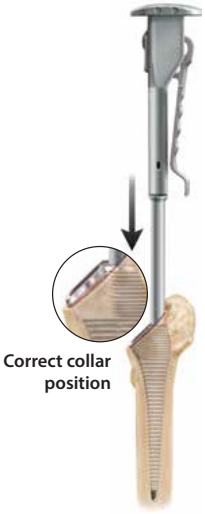
X-ray

1. Femoral Neck Osteotomy

2. Open the Femoral Canal

3. Starter Reamer

4. Starter Broach



5. Femoral Broaching

6. Trial Reduction

7. Stem Insertion

8. Final Trial Reduction

9. Implant Assembly

Chapter 6

Implant 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.

Modular Neck Removal

Should it be necessary, a Profemur® hip stem can be removed in the following manner. The femoral head is removed by placing an osteotome or bone punch on the underside of the femoral head and applying mallet blows upward until the femoral head is removed. With the femoral head removed, thread the 12/14 Adapter (P/N APA00003) over the round taper end of the modular neck. Place the Head/Neck Extractor (P/N APA00001) over the 12/14 adaptor and modular neck, and hand tighten the hex end of the shaft until the base of the extractor rests on the stem, while the fork of the extractor rests under the rim of the adaptor.

CAUTION: The base of the extractor must rest on the top surface of the stem's modular neck pocket, and not on the resected bone.

Attach the Spanner Handle (P/N APA00005) to the hex end of the extractor and rotate clockwise until the neck taper disengages. The Tommy Bar (P/N APA00006) can be inserted into the end of the spanner handle for even greater leverage.

Please note that these instruments are designed for the purpose of removing a neck during the primary surgery. These instruments may or may not be able to provide the force necessary to disengage a connection between components that have been implanted for a longer period of time. In revision cases, removal and replacement of only the modular neck is contraindicated.

12/14 Adapter
P/N APA00003

Head/Neck Extractor
P/N APA00001

Spanner Handle
P/N APA00005

Tommy Bar
P/N APA00006

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 (P/N 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 (P/N PP275400). Using the slide hammer, 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.

NOTE: Modular stem extraction instruments are included in PRGIKIT1.

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.

Femoral Stem Extractor
P/N PPR67688

Hex Screwdriver
P/N PP275400

Universal Stem Extractor
P/N 4700SE05

Slap Hammer
P/N 4700SH0000

Chapter 7

Ordering Information

Profemur® Z Classic Short Neck Stems

PZCLKITA

Catalog No.	Description	Size
PHA0CLS1	Profemur® Z Classic Short Neck Stem Straight	1
PHA0CLS2	Profemur® Z Classic Short Neck Stem Straight	2
PHA0CLS3	Profemur® Z Classic Short Neck Stem Straight	3
PHA0CLS4	Profemur® Z Classic Short Neck Stem Straight	4
PHA0CLS5	Profemur® Z Classic Short Neck Stem Straight	5
PHA0CLS6	Profemur® Z Classic Short Neck Stem Straight	6
PHA0CLS7	Profemur® Z Classic Short Neck Stem Straight	7
PHA0CLS8	Profemur® Z Classic Short Neck Stem Straight	8
PHA0CLS9	Profemur® Z Classic Short Neck Stem Straight	9
PHA0CLE1	Profemur® Z Classic Short Neck Stem Varus 8°	1
PHA0CLE2	Profemur® Z Classic Short Neck Stem Varus 8°	2
PHA0CLE3	Profemur® Z Classic Short Neck Stem Varus 8°	3
PHA0CLE4	Profemur® Z Classic Short Neck Stem Varus 8°	4
PHA0CLE5	Profemur® Z Classic Short Neck Stem Varus 8°	5
PHA0CLE6	Profemur® Z Classic Short Neck Stem Varus 8°	6
PHA0CLE7	Profemur® Z Classic Short Neck Stem Varus 8°	7
PHA0CLE8	Profemur® Z Classic Short Neck Stem Varus 8°	8
PHA0CLE9	Profemur® Z Classic Short Neck Stem Varus 8°	9

Profemur® Plasma Z Classic Short Neck Stems

PPZCKITA

Catalog No.	Description	Size
PHAPCLS1	Profemur® Plasma Z Classic Short Neck Stem Straight	1
PHAPCLS2	Profemur® Plasma Z Classic Short Neck Stem Straight	2
PHAPCLS3	Profemur® Plasma Z Classic Short Neck Stem Straight	3
PHAPCLS4	Profemur® Plasma Z Classic Short Neck Stem Straight	4
PHAPCLS5	Profemur® Plasma Z Classic Short Neck Stem Straight	5
PHAPCLS6	Profemur® Plasma Z Classic Short Neck Stem Straight	6
PHAPCLS7	Profemur® Plasma Z Classic Short Neck Stem Straight	7
PHAPCLS8	Profemur® Plasma Z Classic Short Neck Stem Straight	8
PHAPCLS9	Profemur® Plasma Z Classic Short Neck Stem Straight	9
PHAPCLE1	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	1
PHAPCLE2	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	2
PHAPCLE3	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	3
PHAPCLE4	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	4
PHAPCLE5	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	5
PHAPCLE6	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	6
PHAPCLE7	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	7
PHAPCLE8	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	8
PHAPCLE9	Profemur® Plasma Z Classic Short Neck Stem Varus 8°	9

Profemur® Z Classic Long Neck Stems

PHAZKITA (must be ordered as individual SKUs)

Catalog No.	Description	Size
PHA0S232	Profemur® Z Classic Long Neck Stem Straight	1
PHA0S234	Profemur® Z Classic Long Neck Stem Straight	2
PHA0S236	Profemur® Z Classic Long Neck Stem Straight	3
PHA0S238	Profemur® Z Classic Long Neck Stem Straight	4
PHA0S240	Profemur® Z Classic Long Neck Stem Straight	5
PHA0S242	Profemur® Z Classic Long Neck Stem Straight	6
PHA0S244	Profemur® Z Classic Long Neck Stem Straight	7
PHA0S246	Profemur® Z Classic Long Neck Stem Straight	8
PHA0S248	Profemur® Z Classic Long Neck Stem Straight	9
PHA0E232	Profemur® Z Classic Long Neck Stem Varus 8°	1
PHA0E234	Profemur® Z Classic Long Neck Stem Varus 8°	2
PHA0E236	Profemur® Z Classic Long Neck Stem Varus 8°	3
PHA0E238	Profemur® Z Classic Long Neck Stem Varus 8°	4
PHA0E240	Profemur® Z Classic Long Neck Stem Varus 8°	5
PHA0E242	Profemur® Z Classic Long Neck Stem Varus 8°	6
PHA0E244	Profemur® Z Classic Long Neck Stem Varus 8°	7
PHA0E246	Profemur® Z Classic Long Neck Stem Varus 8°	8
PHA0E248	Profemur® Z Classic Long Neck Stem Varus 8°	9

Profemur® Z Plasma Classic Long Neck Stems

PHAPKITA

Catalog No.	Description	Size
PHAPS232	Profemur® Z Plasma Classic Long Neck Stem Straight	1
PHAPS234	Profemur® Z Plasma Classic Long Neck Stem Straight	2
PHAPS236	Profemur® Z Plasma Classic Long Neck Stem Straight	3
PHAPS238	Profemur® Z Plasma Classic Long Neck Stem Straight	4
PHAPS240	Profemur® Z Plasma Classic Long Neck Stem Straight	5
PHAPS242	Profemur® Z Plasma Classic Long Neck Stem Straight	6
PHAPS244	Profemur® Z Plasma Classic Long Neck Stem Straight	7
PHAPS246	Profemur® Z Plasma Classic Long Neck Stem Straight	8
PHAPS248	Profemur® Z Plasma Classic Long Neck Stem Straight	9
PHAPE232	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	1
PHAPE234	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	2
PHAPE236	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	3
PHAPE238	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	4
PHAPE240	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	5
PHAPE242	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	6
PHAPE244	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	7
PHAPE246	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	8
PHAPE248	Profemur® Z Plasma Classic Long Neck Stem Varus 8°	9

Profemur® Z Stems

4251KITA

Catalog No.	Description	Size
PHA00232	Profemur® Z Stem	1
PHA00234	Profemur® Z Stem	2
PHA00236	Profemur® Z Stem	3
PHA00238	Profemur® Z Stem	4
PHA00240	Profemur® Z Stem	5
PHA00242	Profemur® Z Stem	6
PHA00244	Profemur® Z Stem	7
PHA00246	Profemur® Z Stem	8
PHA00248	Profemur® Z Stem	9

Profemur® Z Plasma Stems

4251KITB

Catalog No.	Description	Size
PHA00260	Profemur® Plasma Z Stem	1
PHA00262	Profemur® Plasma Z Stem	2
PHA00264	Profemur® Plasma Z Stem	3
PHA00266	Profemur® Plasma Z Stem	4
PHA00268	Profemur® Plasma Z Stem	5
PHA00270	Profemur® Plasma Z Stem	6
PHA00272	Profemur® Plasma Z Stem	7
PHA00274	Profemur® Plasma Z Stem	8
PHA00276	Profemur® Plasma Z Stem	9

Profemur® Z Revision Stems

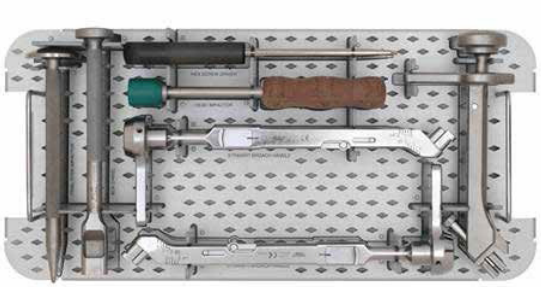
PRZRKITA

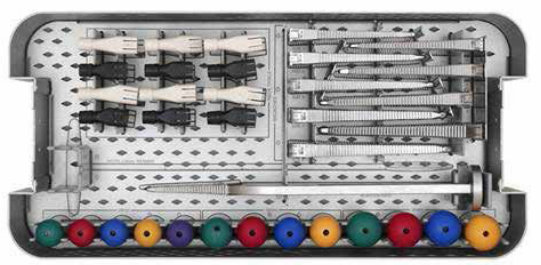
Catalog No.	Description	Size
PHA00606	Profemur® Z Revision Stem	3
PHA00608	Profemur® Z Revision Stem	4
PHA00610	Profemur® Z Revision Stem	5
PHA00612	Profemur® Z Revision Stem	6
PHA00614	Profemur® Z Revision Stem	7
PHA00616	Profemur® Z Revision Stem	8
PHA00618	Profemur® Z Revision Stem	9
PHA00620	Profemur® Z Revision Stem	10
PHA00622	Profemur® Z Revision Stem	11

Profemur® Modular Necks

COCRKITB

Catalog No.	Description
PHAC1202	Straight Short CoCr
PHAC1204	Straight Long CoCr
PHAC1212	Ante/Retro - Varus/Valgus 2 Short CoCr
PHAC1214	Ante/Retro - Varus/Valgus 2 Long CoCr
PHAC1222	Ante/Retro - Varus/Valgus 1 Short CoCr
PHAC1224	Ante/Retro - Varus/Valgus 1 Long CoCr
PHAC1232	Ante / Retro 8° Short CoCr
PHAC1234	Ante / Retro 8° Long CoCr
PHAC1242	Ante / Retro 15° Short CoCr
PHAC1244	Ante / Retro 15° Long CoCr
PHAC1252	Varus / Valgus 8° Short CoCr

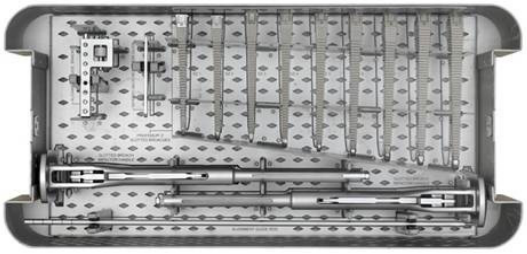




Profemur® Z Instrument Kit

4251KIT1

Catalog No.	Description
APA01070	Profemur® Z Starter Broach
APA01114	Stem Guide Impactor
APA02121	Femoral Head Trial 28mm Short (-3.5mm)
APA02122	Femoral Head Trial 28mm Medium (+0mm)
APA02123	Femoral Head Trial 28mm Long (+3.5mm)
APA02124	Femoral Head Trial 28mm XLong (+7mm)
APA02125	Femoral Head Trial 28mm XXLong (+10.5mm)
APA02142	Femoral Head Trial 36mm Short (-3.5mm)
APA02144	Femoral Head Trial 36mm Medium (+0mm)
APA02146	Femoral Head Trial 36mm Long (+3.5mm)
APA02148	Femoral Head Trial 36mm XLong (+7mm)
APA02151	Femoral Head Trial 32mm Short (-3.5mm)
APA02152	Femoral Head Trial 32mm Medium (+0mm)
APA02153	Femoral Head Trial 32mm Long (+3.5mm)
APA02154	Femoral Head Trial 32mm XLong (+7mm)
APA04241	Profemur® MIS Broach Handle (Qty 2)
APA04244	Broach Handle Alignment Guide Rod (Qty 2)
APA08001	Profemur® Z Slotted Broach Size 1
APA08002	Profemur® Z Slotted Broach Size 2
APA08003	Profemur® Z Slotted Broach Size 3
APA08004	Profemur® Z Slotted Broach Size 4
APA08005	Profemur® Z Slotted Broach Size 5
APA08006	Profemur® Z Slotted Broach Size 6
APA08007	Profemur® Z Slotted Broach Size 7
APA08008	Profemur® Z Slotted Broach Size 8
APA08009	Profemur® Z Slotted Broach Size 9
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
PP275400	Hex Screwdriver
PPF60200	Final Stem Impactor
PPF63011	Tommy Bar
PPR67688	Slap Hammer Stem Extractor
PPR67702	Head Impactor
PPR67704	Box Chisel



Profemur® Z Instruments

PRZSKIT2

Catalog No.	Description
20070055	MIS Broach Alignment Guide Bracket
20070056	MIS Broach Alignment Guide Rod
APA08001	Profemur® Z Slotted Broach Size 1
APA08002	Profemur® Z Slotted Broach Size 2
APA08003	Profemur® Z Slotted Broach Size 3
APA08004	Profemur® Z Slotted Broach Size 4
APA08005	Profemur® Z Slotted Broach Size 5
APA08006	Profemur® Z Slotted Broach Size 6
APA08007	Profemur® Z Slotted Broach Size 7
APA08008	Profemur® Z Slotted Broach Size 8
APA08009	Profemur® Z Slotted Broach Size 9
PTRG0410	Profemur® Neck Resection Guide
SLBROHAN	Slotted Broach Impactor Handle (QTY 2)

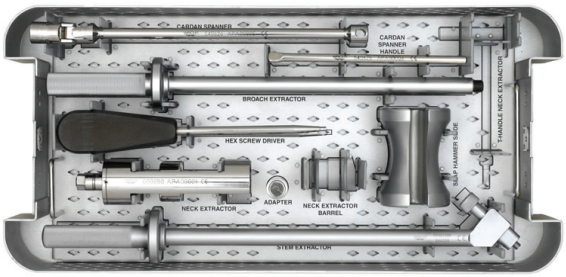
Stem Impactors

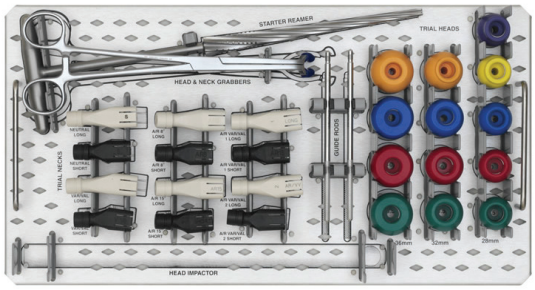
Catalog No.	Description
PRCLIMPT	Profemur® Classic Stem Inserter
PPF60200	Final Stem Impactor (Also included in 4251KIT1)

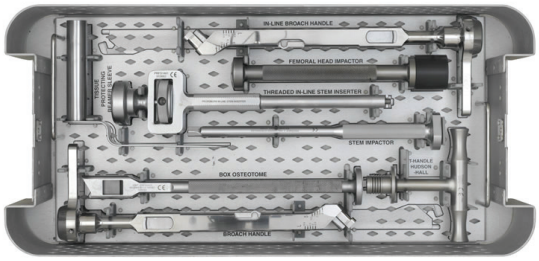
Profemur® Z Revision Instruments

PRZRKIT1

Catalog No.	Description
ZREV0003	Profemur® Z Revision Slot Broach Size 3
ZREV0004	Profemur® Z Revision Slot Broach Size 4
ZREV0005	Profemur® Z Revision Slot Broach Size 5
ZREV0006	Profemur® Z Revision Slot Broach Size 6
ZREV0007	Profemur® Z Revision Slot Broach Size 7
ZREV0008	Profemur® Z Revision Slot Broach Size 8
ZREV0009	Profemur® Z Revision Slot Broach Size 9
ZREV0010	Profemur® Z Revision Slot Broach Size 10
ZREV0011	Profemur® Z Revision Slot Broach Size 11







Profemur® Standard Instruments

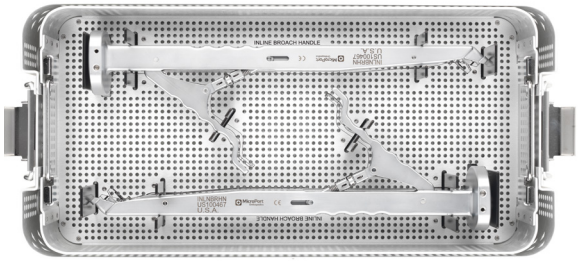
PRGIKIT1

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

Woodpecker Broaching System

4251KT10

Catalog No.	Description
APA00930	Woodpecker
APA00931	Hose Attachment
APA04243	Broach Handle



In-Line Broach Handles

SPBHKIT1

Catalog No.	Description
INLNBRHN	Profemur® In-Line Broach Handle (Qty 2)

Profemur® Z Stems X-Ray Templates

Catalog No.	Description
PRFZXR15	Profemur® Z X-ray Template 15% Magnification
PRZCXR15	Profemur® Z Classic Short Neck Stem X-Ray Template 15% Magnification
PRFNXR15	Profemur® Z Classic Long Neck Stem X-ray Template 15% Magnification
PRZRXR15	Profemur® Z Revision Stem X-ray Template 15% Magnification

Chapter 8

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 and plasma spray 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.

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