Profemur® TL Classic

Hip System: Classic Stems

SURGICAL TECHNIQUE

MicroPort Orthopedics

Integrity In Motion™

Table of Contents

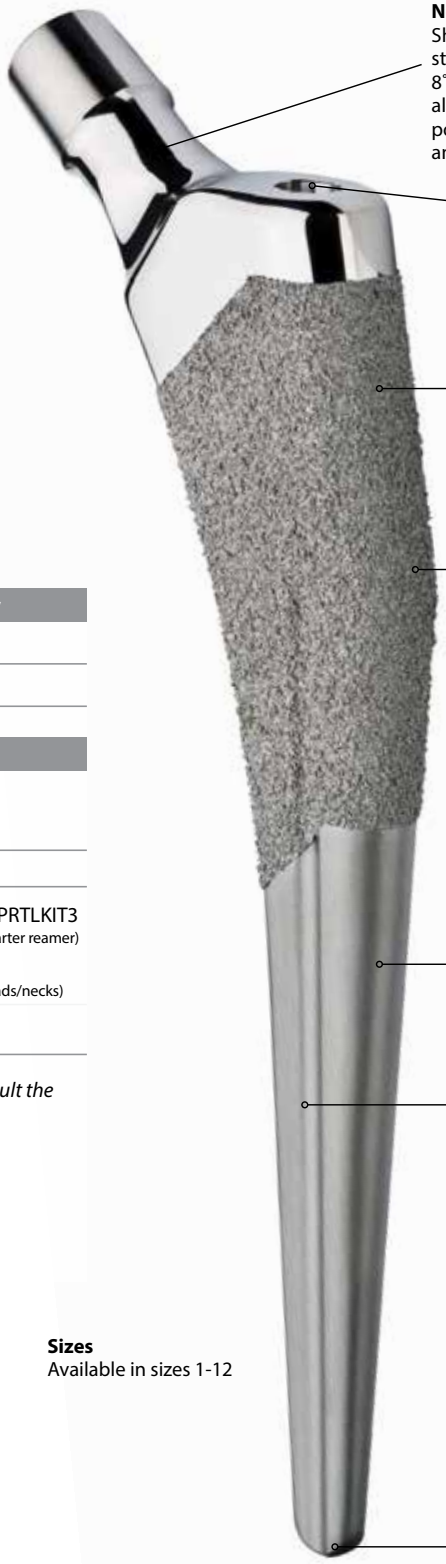
MicroPort Orthopedics recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical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

Chapter 1

Profemur® TL Classic Stem

Product Information

Design Features



Neck Options
Short and long neck lengths, straight (135˚ CCD) and varus 8˚ (127˚ CCD) neck angles allowing for multiple head center positions to meet a range of anatomical needs

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

Lateral Shoulder
Reduced material helps to conserve bone and ease insertion

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

Titanium Stem Surface
Glass-beaded texture

Distal Groove
Designed to assist rotational stability

Sizes
Available in sizes 1-12

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

Abbreviated Technique: Broach Only
Broach to templated size
Implant size corresponding to broach

Ordering Information	
Templates (Short Necks)	PTLCXR15
Templates (Long Necks)	PTLLXR15
Surgical Technique	009790
Instrument Kits	PRTLKIT2 or PRTLKIT3 (broaches and starter reamer) PRGIKIT1 (includes trial heads/necks)
Implants	TLCLKITC

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

Profemur® TL Classic Stems General Specifications

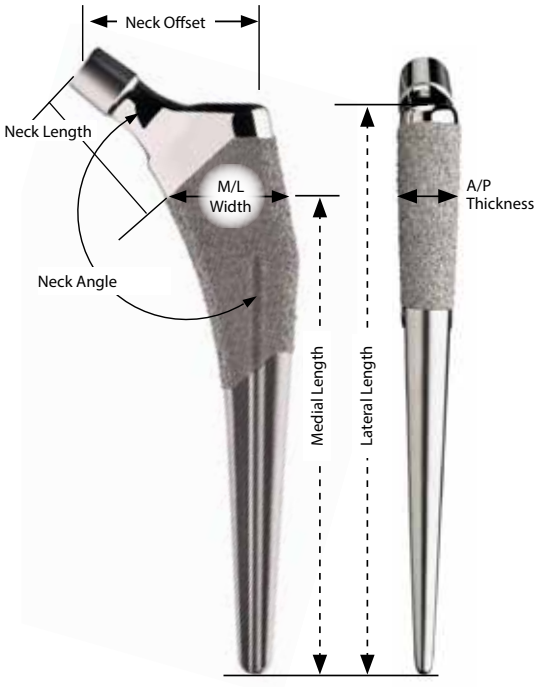
- Stems are made of Titanium alloy with commercially-pure Titanium plasma spray over the proximal region (0.5mm/side)
- M/L Width: 27.3 – 39.2mm
- A/P Thickness: 12.8 – 14.7mm
- Classic Straight neck angle is 135°
- Classic Varus 8° Offset neck angle is 127°

Dimensional Chart

Profemur® TL Classic Hip Stems (Measurements in millimeters)

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

Offset & Neck Length are based on +0 head.
Measurements are stem's substrate.
Profemur® TL Classic long neck stems not available in Europe.



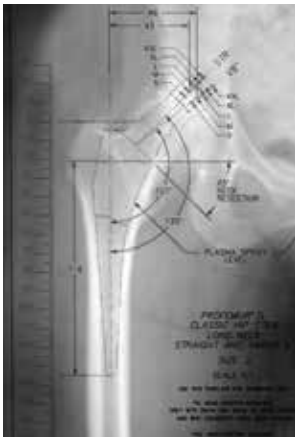
Head Adjustment Chart

(Measurements in millimeters)

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

Chapter 2

Preoperative Planning



Preoperative Planning

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

Accurate preoperative templating requires good quality standardized radiographs of the pelvis and operative hip. To determine limb length discrepancy, draw a line across the bottom of the ischium on the A/P view. The distance from this horizontal reference line to each lesser trochanter should then be measured. The difference between each measured side is the leg length discrepancy. If there is any asymmetry of the pelvis or if landmarks are not clear, other means to determine discrepancy should be used.

Determine the femoral head center. Once the center of rotation for the acetabular component has been established, the center of rotation for the femoral head should be determined. Superimpose the femoral stem templates sequentially on the A/P x-ray with the templates positioned neutrally along the longitudinal axis of the femur. Estimate the metaphyseal and diaphyseal fit and anticipated level of implant insertion using the templates. The approximate femoral size and length of the femoral neck cut can be estimated from the templates. Neck angle and head length which most closely correspond to the patient's femoral head center can be estimated as well. The ideal head will align atop the previously determined center of rotation for the femoral head. In patients with significant deformity of the femoral head, templating can be performed on the opposite hip if necessary.

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

Each circle represents the center of rotation with the corresponding head option (short to XXlong). The circles on the AP template of the stem illustrate the impact of choosing a Varus 8° neck relative to a straight neck.

Chapter 3

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 45º 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.

Profemur® Neck Resection Guide (P/N PTRG0410)

Profemur® Box Chisel P/N PRFS0450

Starter Reamer

Profemur® TL Starter Reamer Chart

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

Femoral Broaching

Starter Reamer

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

Starter Broach

Prepare the femoral canal with the Profemur® TL Broach Size 0 (P/N PRTLBR00 for Femoral Broaching Options 1 and 2, P/N PRTLSB00 for Femoral Broaching Option 3). Staying centered between the anterior and posterior cortices, impact the starter broach until the top of the teeth rests just at or below the level of the neck resection.

Femoral Broaching - Option 1

Attach the broach handle (P/N BROHANTL) to the size 0 broach. Using a mallet, with short, controlled strokes begin broaching. The S (small) and L (long) scale marks on the broach handle correspond to the centers of rotation for respective stem neck lengths and femoral head sizes. Sequentially increase broach size.

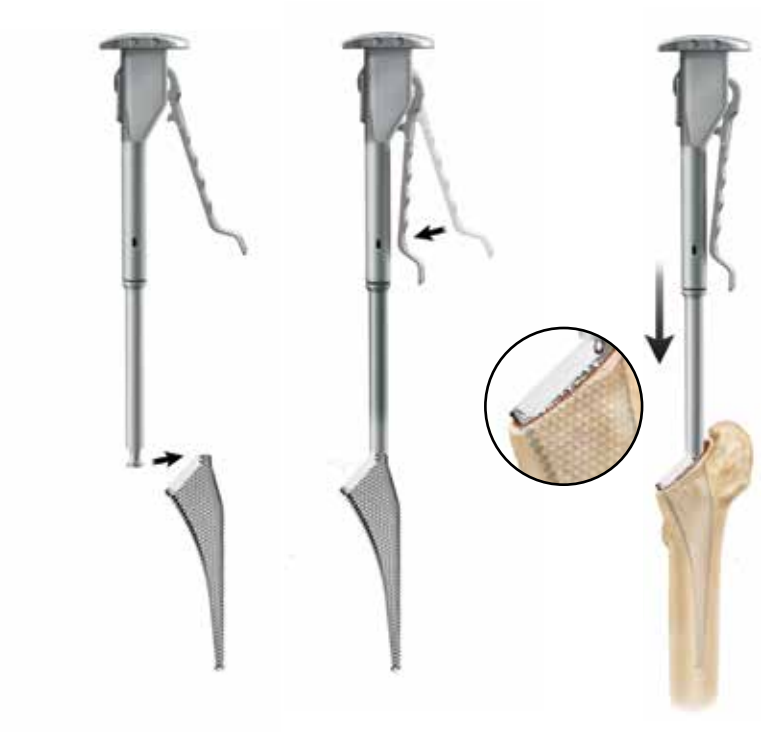
During a posterior approach, a guide rod can be used with the broach handle to provide 20° of implant anteversion. Screw the rod into the superior hole at the proximal end of the broach handle. When inserting the broach, rotate the handle until the guide rod is perpendicular to the floor.

Quick Disconnect T-Handle P/N K0001016

Profemur® TL Starter Reamer P/N PRSTREAM

T Broach Handle P/N BROHANTL

Profemur® TL Broach Size 0 P/N PPRTLBR00



Femoral Broaching - Option 2

Attach the size 0 broach and the customized handle to the Woodpecker, a pneumatic broach inserter. Begin broaching and sequentially increase the broach size.

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

Woodpecker Instrument Kit
P/N 4251KT10

Femoral Broaching - Option 3

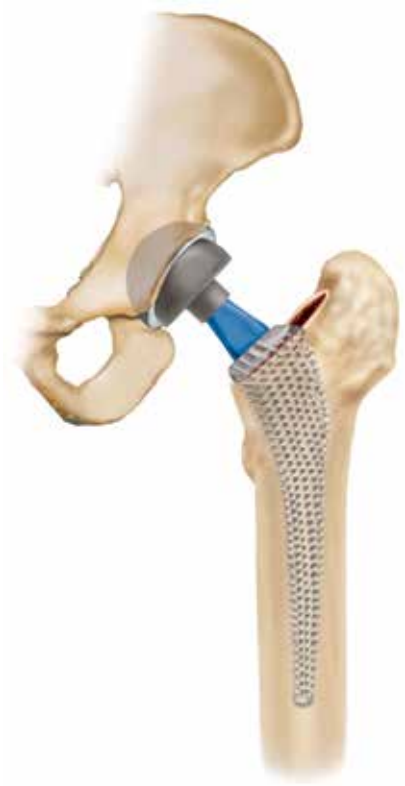
Attach the Slotted Broach Handle (P/N SLBRHAN2) to the Profemur® TL Slotted Broach Size 0 (P/N PRTLSB00). Begin broaching using a mallet with short, controlled strokes. Sequentially broach to the appropriate size, using the Profemur® TL Slotted Broaches (P/Ns PRTLSB01 - PRTLSB12).

The correct 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.

Profemur® TL Slotted Broach Handle
P/N SLBRHAN2

Profemur® TL Slotted Broach Sizes 0 - 12
P/N PRTLSB00 - PRTLSB12



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, and either the Profemur® Trial Head or the Trial Head/Neck Sleeve combination, and perform a trial reduction. Use only the Neutral and V/V 8° angled Profemur® Trial Necks, as they represent the Straight and Varus 8° versions of the Profemur® TL Classic stems. Metal Profemur® Trial Necks (P/Ns APA12102, APA12104, APA12152, 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.

Summary of Profemur® Classic 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.

Femoral Trial Head
P/N APA02144

Stem Insertion

Stem Insertion

Insert the femoral implant into the canal and seat itas far as possible by hand while maintaining proper version. Use the Profemur® Classic Stem Impactor (P/N PRCLIMPT) to engage the oval slot on the lateral shoulder for rotational control. Then, use the Final Stem Impactor (P/N PPF60200) to engage the dimple on the lateral shoulder and apply uni-directionally load. Fully seat the implant using short, controlled strokes with a surgical mallet. Typically, the implant is seated with the base of the polished neck or the underside of the collar at the resection cut.

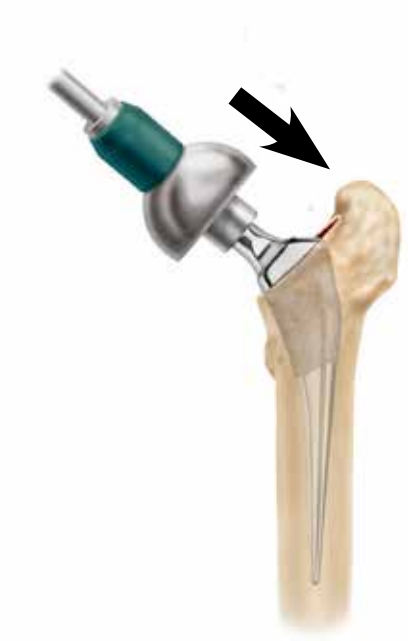
The implant may sit 1-2mm more proud than templated due to the additional 0.5mm thickness per side of the plasma. The difference can be addressed during the final trial reduction by selecting the proper femoral head.

Final Trial Reduction

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

Profemur® Classic Stem Inserter
P/N PRCLIMPT

Final Stem Impactor
P/N PPF60200



Implant Assembly

To properly assemble and impact a Profemur® femoral head onto the neck of a Classic stem, the following procedure is recommended:

Step A

Suction any fluid from the femoral head implant pocket. Ensure that both the femoral head implant pocket and the head of the neck on the Classic stem are clean and dry prior to assembly.

Step B

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 C

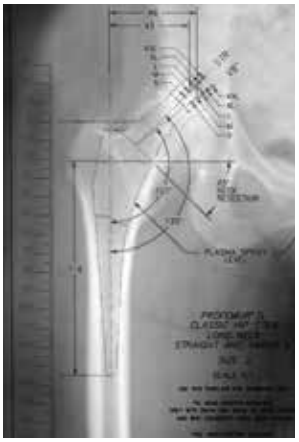
Affix the femoral head to the neck. Using the head impactor instrument, strike the impactor with three very firm blows with a mallet to securely fix the head to the neck of the stem.

Note: *If using a ceramic head, place the head on the neck by hand, push and turn the head 180° to securely lock it in place.*

Chapter 4

Technique Overview

1. X-ray



2. Femoral Neck Osteotomy

3. Open the Femoral Canale

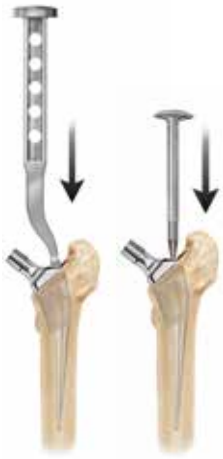
4. Starter Reamer

5. Femoral Broaching

or

6. Trial Reduction

7. Stem Insertion



8. Implant Assembly

Profemur® TL Classic Stem Removal

Stem Removal

Stem Removal

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

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

PERFECTA® Universal Stem Extractor
P/N 4700SE05

Slap Hammer
P/N 4700SH0000

Chapter 5

Ordering Information

Profemur® TL Classic Stems

TLCLKITC

Profemur® TL Classic Stems with Short Necks

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

Profemur® TL Classic Stems with Long Necks

Catalog No.	Neck Angle	Size
PRTLSL21	Straight	1
PRTLSL22	Straight	2
PRTLSL23	Straight	3
PRTLSL24	Straight	4
PRTLSL25	Straight	5
PRTLSL26	Straight	6
PRTLSL27	Straight	7
PRTLSL28	Straight	8
PRTLSL29	Straight	9
PRTLSL30	Straight	10
PRTLSL31	Straight	11
PRTLSL32	Straight	12
PRTLEL21	Varus 8˚	1
PRTLEL22	Varus 8˚	2
PRTLEL23	Varus 8˚	3
PRTLEL24	Varus 8˚	4
PRTLEL25	Varus 8˚	5
PRTLEL26	Varus 8˚	6
PRTLEL27	Varus 8˚	7
PRTLEL28	Varus 8˚	8
PRTLEL29	Varus 8˚	9
PRTLEL30	Varus 8˚	10
PRTLEL31	Varus 8˚	11
PRTLEL32	Varus 8˚	12

Instruments

PRTLKIT2

Profemur® TL Instruments

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

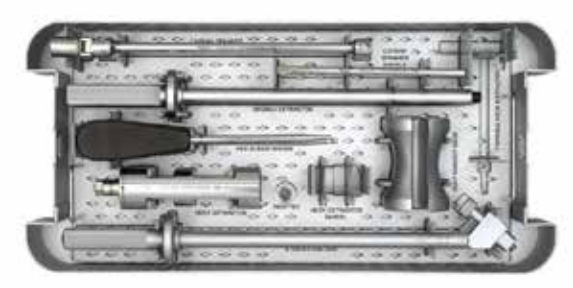
PRTLKIT3

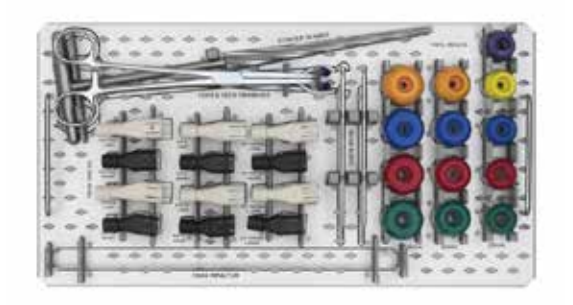
Profemur® TL Slotted Broach Instruments

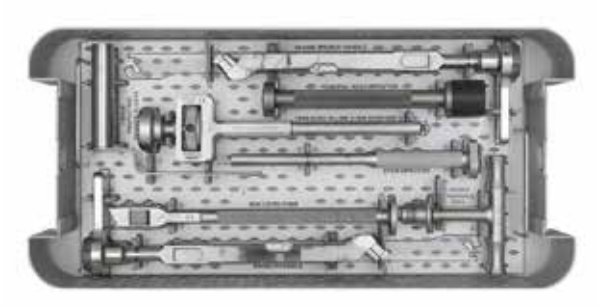
Catalog No.	Description	Quantity
PRTLSB00	Profemur® TL Slotted Broach Size 0	1
PRTLSB01	Profemur® TL Slotted Broach Size 1	1
PRTLSB02	Profemur® TL Slotted Broach Size 2	1
PRTLSB03	Profemur® TL Slotted Broach Size 3	1
PRTLSB04	Profemur® TL Slotted Broach Size 4	1
PRTLSB05	Profemur® TL Slotted Broach Size 5	1
PRTLSB06	Profemur® TL Slotted Broach Size 6	1
PRTLSB07	Profemur® TL Slotted Broach Size 7	1
PRTLSB08	Profemur® TL Slotted Broach Size 8	1
PRTLSB09	Profemur® TL Slotted Broach Size 9	1
PRTLSB10	Profemur® TL Slotted Broach Size 10	1
PRTLSB11	Profemur® TL Slotted Broach Size 11	1
PRTLSB12	Profemur® TL Slotted Broach Size 12	1
PRSTREAM	Profemur® TL Starter Reamer	1
SLBRHAN2	Profemur® TL Slotted Broach Handle	2

Stem Impactors

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







Instruments

PRGIKIT1

Profemur® Standard Instrument Kit

Catalog No.	Description
APA02121	FEMORAL TRIAL HEAD 28MM SHORT
APA02122	FEMORAL TRIAL HEAD 28MM MEDIUM
APA02123	FEMORAL TRIAL HEAD 28MM LONG
APA02124	FEMORAL TRIAL HEAD 28MM XLONG
APA02125	FEMORAL TRIAL HEAD 28MM XXLONG
APA02151	FEMORAL TRIAL HEAD 32MM SHORT
APA02152	FEMORAL TRIAL HEAD 32MM MEDIUM
APA02153	FEMORAL TRIAL HEAD 32MM LONG
APA02154	FEMORAL TRIAL HEAD 32MM XLONG
APA02142	FEMORAL TRIAL HEAD 36MM SHORT
APA02144	FEMORAL TRIAL HEAD 36MM MEDIUM
APA02146	FEMORAL TRIAL HEAD 36MM LONG
APA02148	FEMORAL TRIAL HEAD 36MM XLONG
APA00001	HEAD/NECK EXTRACTOR
APA00003	HEAD/NECK EXTRACTOR ADAPTOR 12/14
APA00005	HEAD/NECK EXTRACTOR CARDAN SPANNER HEX
APA00006	HEAD/NECK EXTRACTOR TOMMY BAR
PPR67688	SLAP HAMMER STEM EXTRACTOR
PRFS0462	Profemur® BROACH EXTRACTION SHAFT
PP275400	HEX SCREWDRIVER
PRFS0450	Profemur® BOX CHISEL
4400FI0000	FEMORAL HEAD IMPACTOR
K0001016	QUICK DISCONNECT T-HANDLE
PRFS0451	Profemur® TISSUE PROTECTING SLEEVE
APA04750	STARTER REAMER
APA04244	BROACH HANDLE REFERENCE ROD (2)
APA04241	Profemur® MIS BROACH HANDLE
20070050	MODULAR NECK INSERTER
PRFS1461	Profemur® THREADED IN-LINE STEM INSERTER
PRFS0460	Profemur® SCREWDRIVER INSERTER
APA11102	PLASTIC TRIAL NECK NEUTRAL SHORT
APA11104	PLASTIC TRIAL NECK NEUTRAL LONG
APA11112	PLASTIC TRIAL NECK AR/VV 1 SHORT
APA11114	PLASTIC TRIAL NECK AR/VV 1 LONG
APA11122	PLASTIC TRIAL NECK AR/VV 2 SHORT
APA11124	PLASTIC TRIAL NECK AR/VV 2 LONG
APA11132	PLASTIC TRIAL NECK A/R 8° SHORT
APA11134	PLASTIC TRIAL NECK A/R 8° LONG
APA11142	PLASTIC TRIAL NECK A/R 15° SHORT
APA11144	PLASTIC TRIAL NECK A/R 15° LONG
APA11152	PLASTIC TRIAL NECK V/V 8° SHORT
APA11154	PLASTIC TRIAL NECK V/V 8° LONG

Instruments

4251KT10
Woodpecker Broaching System Express Instrument Kit

Catalog No.	Description
APA00930	Woodpecker
APA00931	Hose Attachment
APA00941	Case
APA04243	Broach Handle

Templates

Profemur® TL Stems X-Ray Templates

Catalog No.	Description
PTLCXR15	Profemur® TL Classic Short Necks X-Ray Template 15% Magnification
PTLLXR15	Profemur® TL Classic Long Necks X-Ray Template 15% Magnification

Chapter 6

Indications and Warnings

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.

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). Scratching of femoral heads and proximal stem tapers 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 taper of the femoral component 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 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 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.