MicroPort Orthopedics

Profemur®

TL2

Surgical Technique

PROFEMUR® TL2 HIP SYSTEM

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 package insert is available on the website listed.

Package inserts can be found under:
Prescribing Information on microportortho.com

Please contact your local MicroPort Orthopedics representative for product availability.

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Foreword

Designed for primary hip replacement surgery, the Profemur® TL2 hip stem is a dual tapered wedge stem with an innovative geometry. It features a reduced lateral shoulder convenient for tissue-sparing surgical techniques. Allowing for three point fixation, the stem is shaped to contact cortical bone medially and laterally, while conserving cancellous bone anteriorly and posteriorly. Plasma spray coating and anteroposterior taper allow contact in the frontal plane, while rotational stability is enhanced via distal grooves.

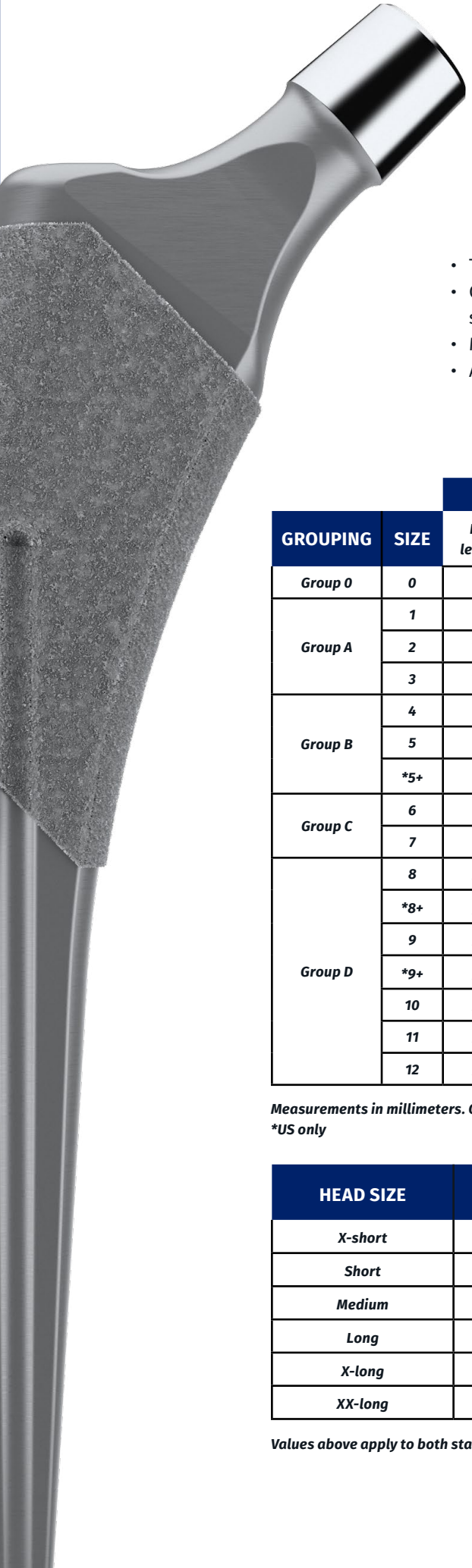
Product information

ABBREVIATED TECHNIQUE: BROACH ONLY
Broach to templated size. Implant size corresponds to broach size.

ORDERING INFORMATION	
Ordering Guide	019884/A
Templates	PRTL2X15 ***(standard and high offset)***
Surgical technique	019564/E
Instrument kits	PRTL2KT1 ***(Broach and trial necks)***
	PRGIKIT1 ***(Includes trial heads/necks)***
Stem impactor	PRCLIMPT ***(Classic inserter)***
Implants	PRTL2KTA

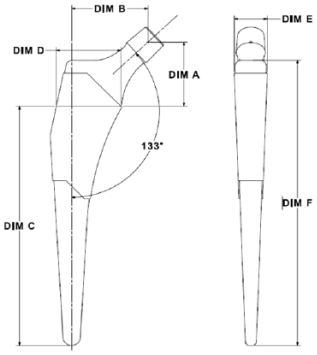
SIZES	
Neck	Standard & high offset: Sizes 0–12
Stem	

For additional risk information, please consult the instructions for use package insert.



General specifications

- Titanium alloy stems
- Commercially-pure titanium plasma spray over proximal region (0.5mm/side)
- M/L Width: 27–40mm
- A/P Width: 13–17mm



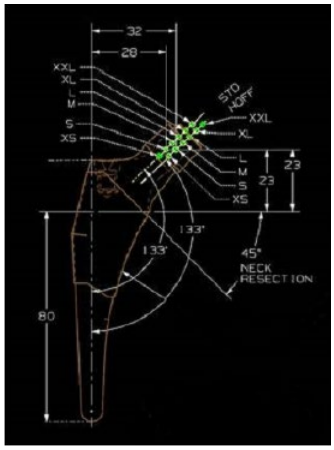
		STANDARD		HIGH OFFSET		STEM MEASUREMENTS				
GROUPING	**SIZE**	***Leg length***	***Neck offset***	***Leg length***	***Neck offset***	***Medial length***	***M/L width***	***A/P width***	***Lat length***	***Neck angle***
Group 0	***0***	26	31	26	35	78	27	13	99	133
Group A	***1***	28	32	28	38	109	28	15	129	133
	2	28	33	28	39	111	28	15	131	133
	3	28	34	28	40	114	30	15	131	133
Group B	***4***	32	36	32	42	117	30	15	139	133
	5	32	37	32	43	119	31	16	142	133
	****5+***	33	38	33	44	119	31	16	142	133
Group C	***6***	33	38	33	46	122	32	16	145	133
	7	33	39	33	47	125	32	16	148	133
Group D	***8***	34	41	34	49	127	34	16	149	133
	****8+***	34	42	35	50	126	34	16	149	133
	9	34	42	34	50	130	35	16	152	133
	****9+***	34	43	35	51	129	35	16	152	133
	10	34	43	34	51	135	37	16	157	133
	11	34	44	34	52	140	39	17	162	133
	12	34	46	34	54	146	40	17	168	133

Measurements in millimeters. Offset and leg length are based on +0 head.
****US only***

HEAD SIZE	NECK LENGTH ADJUSTMENT	LEG LENGTH	OFFSET
X-short	-7.0	-4.8	-5.1
Short	-3.5	-2.4	-2.6
Medium	0.0	+0.0	+0.0
Long	+3.5	+2.4	+2.6
X-long	+7.0	+4.8	+5.1
XX-long	+10.5	+7.2	+7.7

Values above apply to both standard and high offset stems due to their sharing the same CCD angle of 133 degrees.

Preoperative Planning



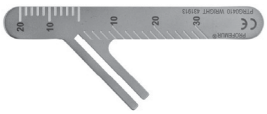
CAUTION: Preoperative templating is intended for estimation purposes only.

Final component size and position should be determined intraoperatively. Accurate pre-operative templating requires good quality standardized radiographs of the pelvis and operative hip. To determine leg length discrepancy, draw a line across the bottom of the ischium on the A/P view. The distance from this horizontal reference line to each lesser trochanter should then be measured. The difference between each measured side is the leg length discrepancy. If there is any asymmetry of the pelvis or if landmarks are not clear, other means to determine discrepancy should be used. Determine the femoral head center. Once the center of rotation for the acetabular component has been 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 the corresponding head option (X Short to XX Long). The circles on the A/P template of the stem illustrate the impact of choosing a standard offset relative to a high offset neck. 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.

Surgical Technique

Femoral neck osteotomy

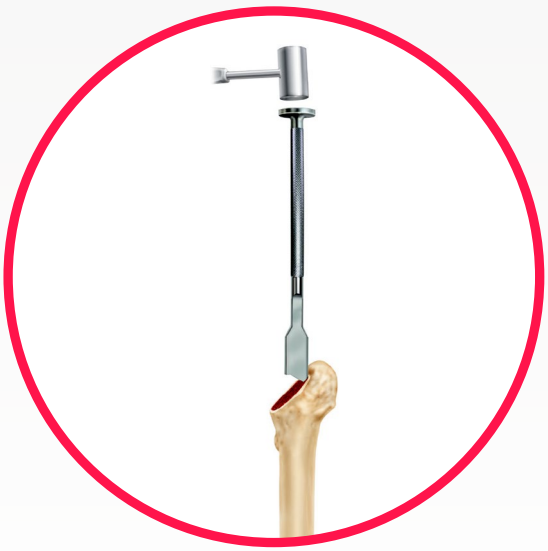
Using the greater trochanter or lesser trochanter as a reference, resect the neck at a 45˚ angle to the longitudinal axis of the femur. The Profemur® Neck Resection Guide (P/N PTRG0410) is available to help establish the angle of resection.



Profemur® neck resection guide
P/N PTRG0410

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® box chisel
P/N PRFS0450

Profemur® tl starter reamer
P/N PRSTREAM

Quick disconnect T-handle
P/N K0001016

Inline broach handle
P/N INLNBRHN

Profemur® TL2 broach size 0
P/N PRTL2B00

IMPLANT SIZE	MEDIAL IMPLANT LENGTH *(mm)*
0	78
1	109
2	111
3	114
4	117
5	119
6	122
7	125
8	126
9	129
10	134
11	139
12	146

Starter reamer

Enter the femoral canal with the Profemur® TL2 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 over-reaming 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® TL2 Broach Size 0 (P/N PRTL2B00). Staying centered between the anterior and posterior cortices, impact the starter broach until the top of the teeth rests just at or below the level of the neck resection.

Femoral broaching

Attach the preferred broach handle (P/N INLNBRHN is shown) to the Profemur® TL2 Broach Size 1. Using a mallet, with short, controlled strokes begin broaching. 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.

Potential differences between broached and templated sizes:

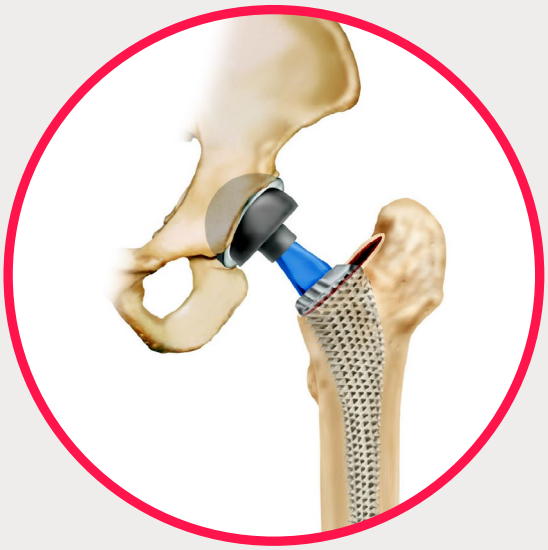
1. The quality of bone plays an integral role in sizing. For soft bone, the broach may seat further than the template indicates. An implant larger than the templated size may be required. Patients with strong, healthy bone might require an implant smaller than the templated size.

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

Trial reduction

The trial necks for the Profemur® TL2 are specific to the implant size and therefore have to match the size of the in situ broach. Clear identification for the sizing is engraved on the trial neck, in addition to color coding. The proximal groove below the round trunnion indicates the proximal/lateral side of the trial neck. Ensure proper positioning of the trial neck with visual and tactile confirmation. Select the appropriate trial neck (see below)and trial head (P/Ns APA02121 - APA02154) and perform a trial reduction. Once a well balanced hip has been created with a trial head and trial neck, remove the broach.



- Straight (133°) necks create a neutral neck axis.
- Size 0 has 4mm of direct offset between standard and lateralized
- Sizes 1-5 have 6mm of direct offset between standard and lateralized
- Sizes 6-12 have 8mm of direct offset between standard and lateralized

GROUPING	SIZES	TRIAL NECK COLOR	P/N
Group 0	0		PRTL2NS0 PRTL2NE0
Group A	1		PRTL2NSA PRTL2NEA
	2		
	3		
Group B	4		PRTL2NSB PRTL2NEB
	5		
	5+		
Group C	6		PRTL2NSC PRTL2NEC
	7		
Group D	8		PRTL2NSD PRTL2NED
	8+		
	9		
	9+		
	10		
	11		
	12		

Profemur TL2 trial neck
Size 0 P/N
PRTL2NS0
PRTL2NE0

Profemur TL2 trial neck
Size 1-3 P/N
PRTL2NSA
PRTL2NEA

Profemur TL2 trial neck
Size 4-5 P/N
PRTL2NSB
PRTL2NEB

Profemur TL2 trial neck
Size 6-7 P/N
PRTL2NSC
PRTL2NEC

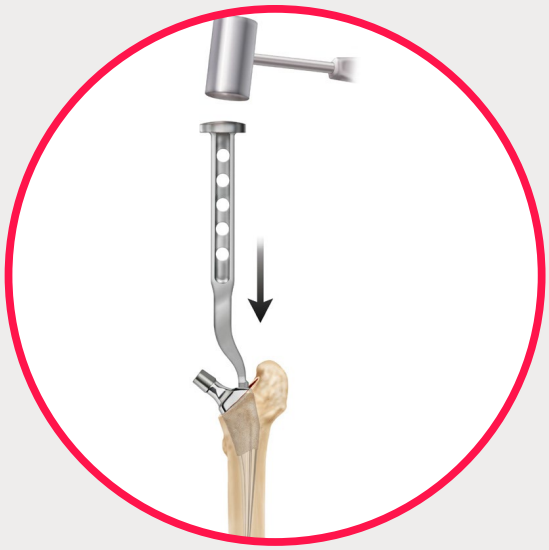
Profemur TL2 trial neck
Size 8-12 P/N
PRTL2NSD
PRTL2NED

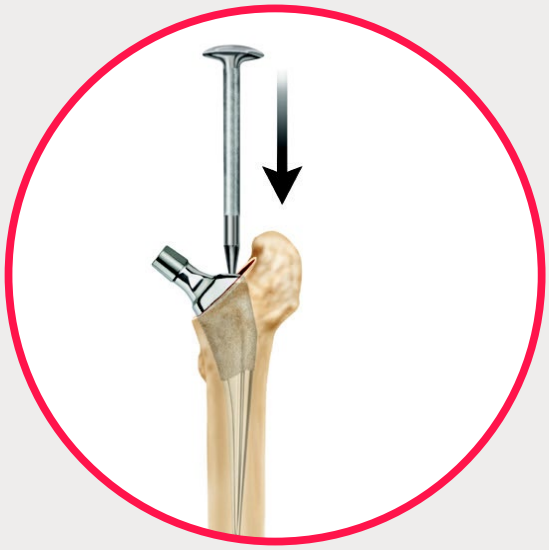
PRTL2NS* = Standard

PRTL2NE* = High offset

Profemur® classic stem inserter
P/N PRCLIMPT

Final stem impactor
P/N PPF60200





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 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 a unidirectional load. Fully seat the implant using short, controlled strokes with a surgical mallet. Typically, the implant is seated along the neck-plasma spray line at the level of 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 the trial heads to reconfirm stability, range of motion and leg length.

Head assembly

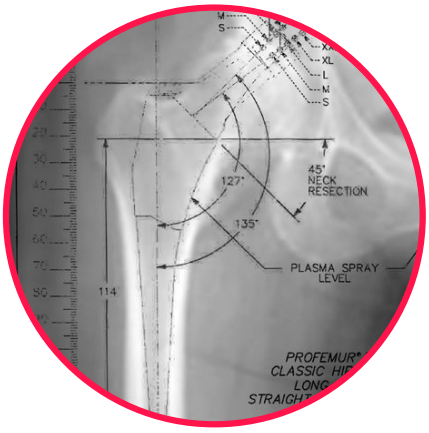
Ensure the stem taper is clean and dry prior to assembly,and then affix the femoral head to the neck. Using the head impactor instrument, strike the impactor with three very firm blows with a mallet to securely fix the head to the stem.

NOTE: Place a femoral head impactor with a plastic impaction tip (such as P/N 4400FI0000 or PPR67702) on a ceramic femoral head, and align the impactor with the femoral neck axis of the stem implant.

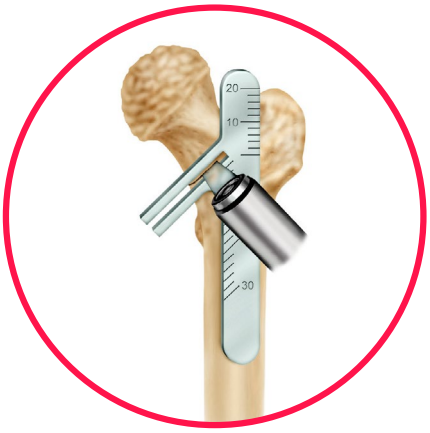
With a moderate tap of the hammer in the axial direction, firmly impact the ceramic femoral head on the stem taper until it is fully seated. Position the leg such that the knee is supported by an assistant on the opposite side of the table. By resting the patient's knee against the mid-section of the assistant, this will provide counter-force against the mallet blows to ensure the impaction load transfer to the neck junction.

Technique Overview

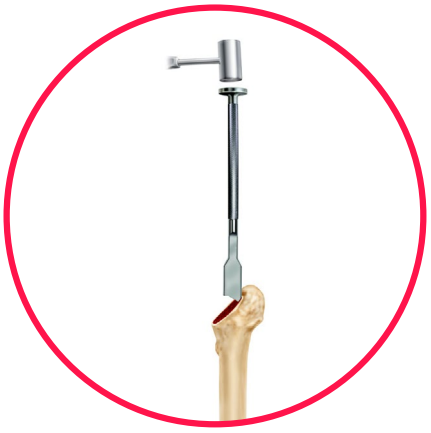
1 *X-ray*



2 *Femoral neck osteotomy*



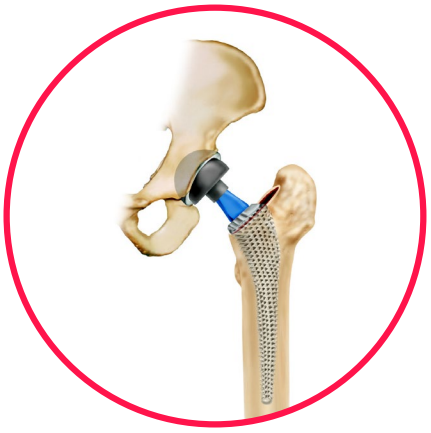
3 *Open the femoral canal*



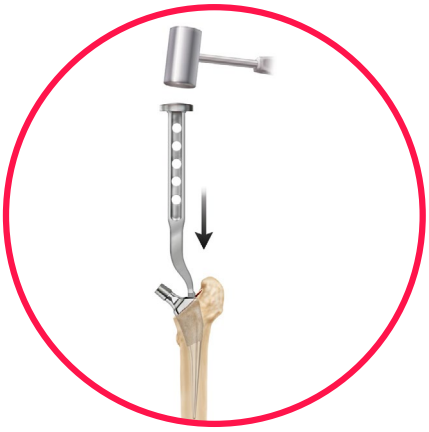
4 *Starter reamer*

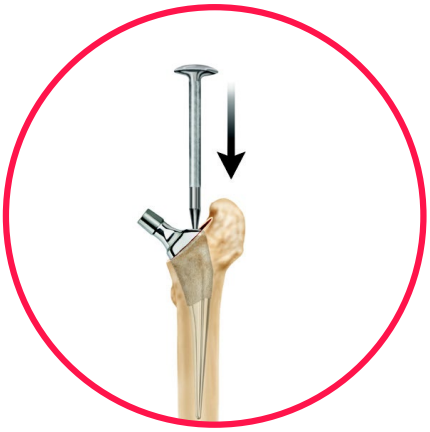
5 *Femoral broaching*

6 *Trial reduction*

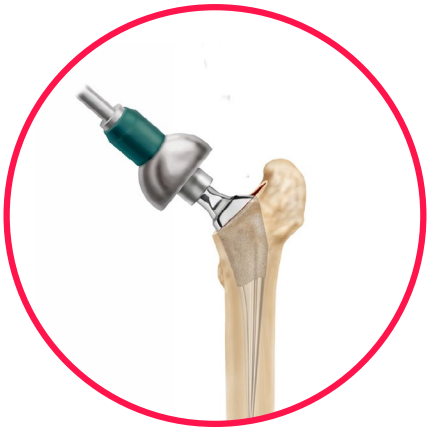


7 *Stem insertion*





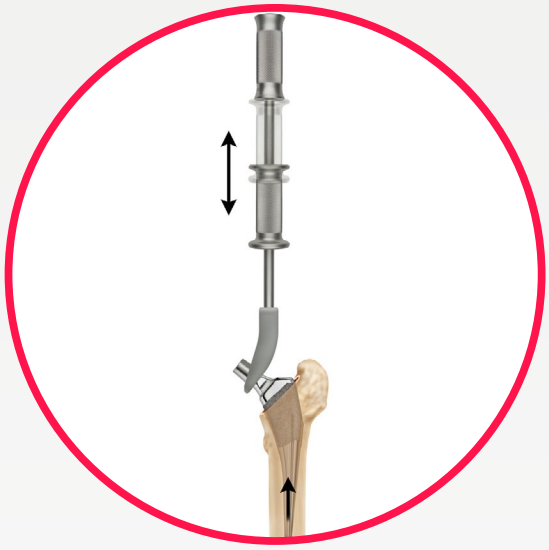
8 *Head assembly*



Implant Removal

Perfecta® universal stem extractor
P/N 4700SE05

Slap hammer
P/N 4700SH0000



NOTE: 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.

Stem removal

Should the removal of a Profemur® TL2 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: Stem extraction instruments must be ordered separately.

Indications and Warnings

Compatibility

Profemur® TL2 Stem sizes 1-12 can be used with all commercially available MicroPort femoral heads possessing the MicroPort 12/14 SLT Taper, except Profemur® TL2 Stem size 0, which will be not be compatible to be used with any Extra Short (XS) offset femoral heads MicroPort has commercially available. However, it will be compatible to be used with all other available femoral head sizes, Small to XX-Long (S-XXL). Each femoral head possessing the MicroPort 12/14 SLT Taper can be further mated with a commercially available MicroPort acetabular cup system.

Important

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Notes

Notes

MicroPort Orthopedics Inc.
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866 872 0211

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

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