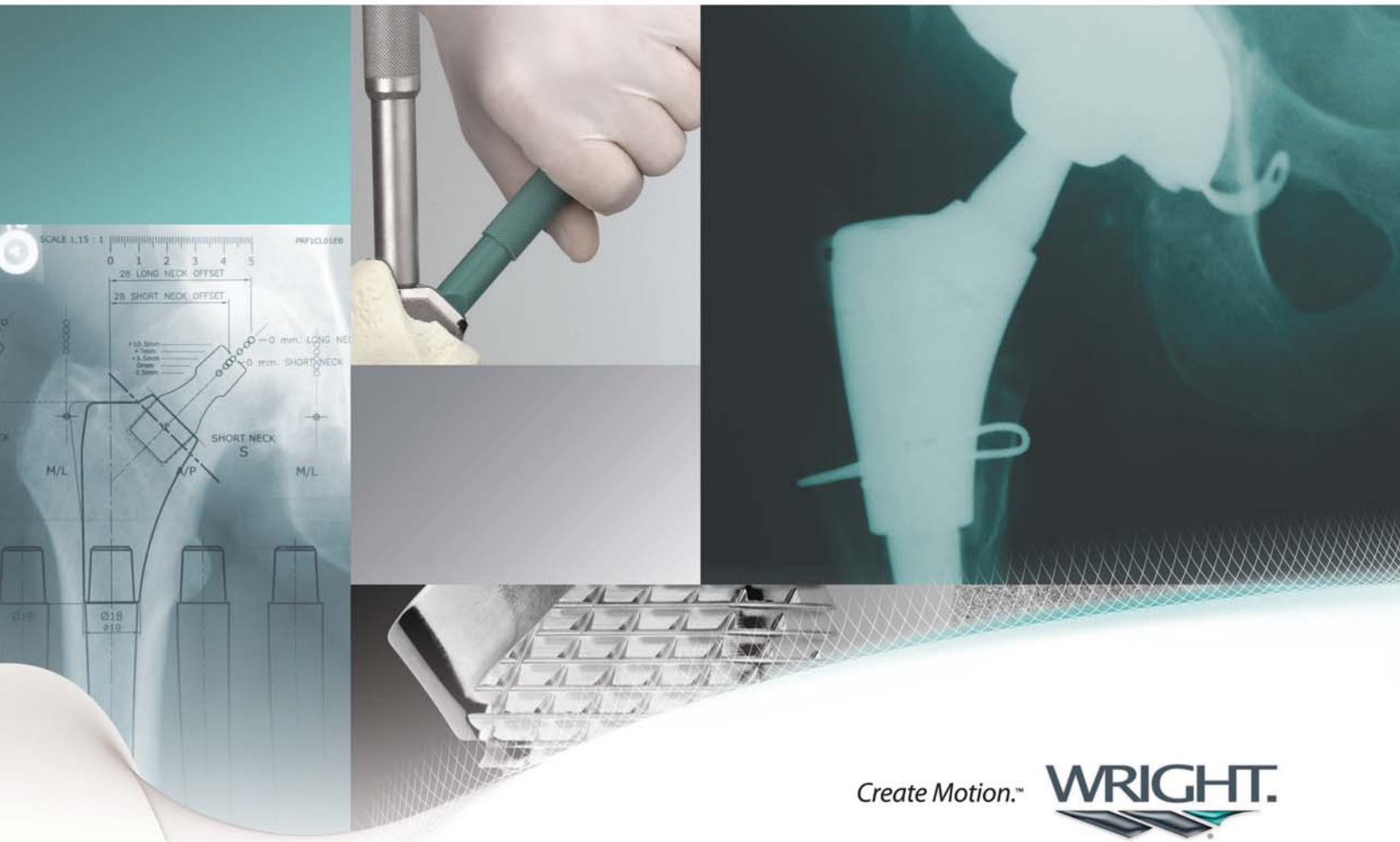
PROFEMUR® R

Total Hip System | Tapered Stems

SURGICAL TECHNIQUE



Create Motion.™ WRIGHT.

Surgical technique as described by R. Scott Corpe, M.D., Kurt Merke, M.D., Kent Samuelson, M.D. and Timothy Young, D.O.

Total Hip Arthroplasty is one of the largest challenges facing orthopaedic surgeons today. Bone quality, fixation, and soft tissue balancing are just a few of the issues that must be addressed.

The PROFEMUR® R Hip System provides the surgeon with a modular approach to address these issues. Proximal and distal segments allow easy matching of implant to host bone. Splined, tapered and plasma sprayed components provide optional fixation methods. The unique modular neck component allows soft tissue balancing and easy restoration of hip joint center of rotation. This modular approach to implant design provides the surgeon with unsurpassed options for revision hip replacement.

FEATURES AND BENEFITS

PROXIMAL BODIES

- Titanium Alloy
- Porous plasma sprayed and grit-blasted textures
- Distal locking screw
- Proximal body hole plug

FEMORAL NECKS

- Titanium Alloy
- 12 sizes
- 6 long, 6 short lengths
- 6 styles
  - Neutral
  - 8º varus/valgus
  - 8º anteversion/retroversion
  - 15º anteversion/retroversion
  - Anteversion/retroversion varus/valgus 1
  - Anteversion/retroversion varus/valgus 2
- Slim neck geometry
- Polished surface
- Each neck is reversible – resulting in twice as many options

DISTAL STEMS

TAPERED WITH SPLINES

- Three lengths
  - 135mm straight
  - 175mm bowed
  - 215mm bowed
- Grit-blasted surface texture
- Titanium Alloy
- Tapered Splines

PROFEMUR® R
total hip **SYSTEM**

SURGICAL TECHNIQUE

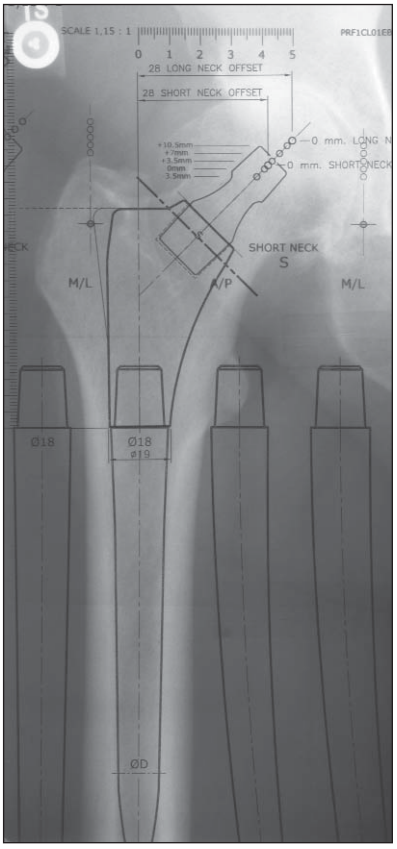


FIGURE 1

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for informational purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to the use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Wright Medical Technology, Inc.

PREOPERATIVE EVALUATION

When positioning the PROFEMUR® R Hip System, it has been found advantageous to seat the implant at a depth that would allow a short neck with a medium head to approximate the height of the center of the femoral head. Seating the implant at this level will allow the most versatility from the modular head and necks during the trialing process. This position is predominantly determined through preoperative x-ray templating | **FIGURE 1.**

NOTE | Templating of the proximal body in the lateral view is as important as templating in the A/P view. In many cases, a proximal body may appear to be well sized in the A/P view, but too large in the lateral view.

RECOMMENDED TEMPLATING PROCEDURE

When templating, appropriate proximal body size is determined first. However, the proximal body and distal stem templates should be used in conjunction to ensure accurate alignment. This is achieved when cortical contact is obtained on the medial, lateral, anterior and posterior sides of the implant. This will reduce the likelihood of stress shielding. Reference the implant position to a bone landmark to use as a guide for distal and proximal reaming to ensure the final implant will sit at the desired level.

CAUTION | PRE-OPERATIVE TEMPLATING IS INTENDED FOR ESTIMATING PURPOSES ONLY. FINAL COMPONENT SIZE IS DETERMINED INTRAOPERATIVELY.

From this point, the appropriate distal stem is determined by finding the stem size that provides the most ideal canal fit. Once again, the proximal body and distal stem templates should be used in conjunction to ensure accurate alignment.

PROFEMUR® R
total hip **SYSTEM**

SURGICAL TECHNIQUE FOR TAPERED STEMS
as described by Kent Samuelson, MD

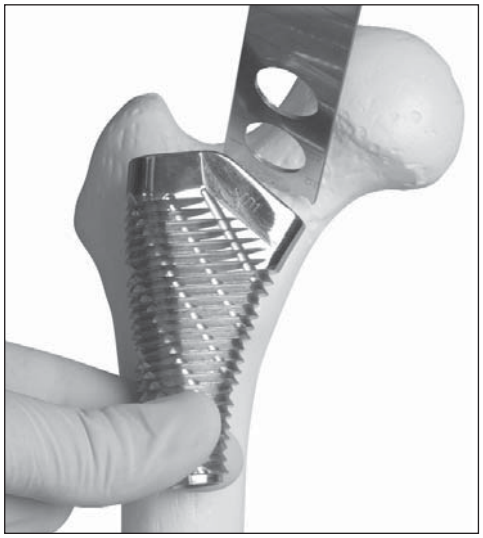


FIGURE 2

NECK RESECTION

The femoral neck should be resected approximately 20 millimeters proximal to the lesser trochanter at a 45-degree angle to the shaft of the femur. A proximal rasp may be utilized as a resection template. | **FIGURE 2**

CANAL PREPARATION

The femoral canal may be initially prepared by utilizing the initial canal reamer | **FIGURE 3** or the 9mm cylindrical starter reamer. Any bone cement, fibrous membrane, or excess tissue must be completely removed from the femoral canal. The cylindrical starter reamer may also be used to evaluate and probe the femoral canal; assessing orientation and curvature of the femoral shaft. Prior to reaming the femoral canal, the medial aspect of the greater trochanter should be cleared of any overhanging bone to facilitate neutral alignment of the femoral reaming and proximal rasp instruments. Canal preparation begins with the smallest reamer that fits into the canal and progresses sequentially.

FIGURE 3

FIGURE 4

FIGURE 5

DISTAL REAMING

Manual reaming of the femur using the t-handle is recommended for maintaining alignment control, minimizing heat generation, and avoiding overreaming of the canal. If using the straight reamers, axial alignment must be maintained at all times during the reaming process to ensure neutral position of the femoral prosthesis. To avoid varus positioning of the reamers, apply lateral pressure; taking care not to endanger the greater trochanter. (Reaming to two sizes less than what was preoperatively templated is recommended to limit the risk of oversizing the distal canal.)

NOTE | The greater trochanter may be difficult to discern due to soft tissue coverage; however, its tip may be found by probing with an 18-gauge needle. Table 2 lists reamer and implant combinations which will achieve the recommended distal canal press-fit.

FOR STRAIGHT STEMS

Cylindrical reamers are provided in increments of 0.5mm diameters, and are notched in 10mm increments | **FIGURE 4.** Prior to reaming, the correct reaming depth is determined by adding the lengths of the templated proximal body and distal stem. It is suggested that the reamer be advanced 15mm deeper than the templated length | **TABLE 1.** Proper depth of the cylindrical reamers is generally indicated when the appropriate depth on the reamer aligns with the tip of the greater trochanter.

TABLE 1 – RECOMMENDED REAMING DEPTHS

	DISTAL STEM LENGTHS (mm)			
PROXIMAL BODY LENGTH	**135**	**175 (Bowed)**	**215 (Bowed)**	
50mm (X-Small Modular)	200	240	280	REAMING DEPTHS
54mm (Small or Grit Blast X-Small)	204	244	284	
67mm (Standard 1-4)	217	257	297	
80mm (Large)	230	270	310	

*Reaming depths include an additional 15mm.

FOR BOWED STEMS

NOTE | Flexible reamers, in conjunction with the distal broaches, may be utilized to preliminarily prepare the canal for the bowed tapered stems | FIGURE 5. However, care should be taken when using flexible reamers. They may preclude achieving a tight fit over a sufficient area. To implant bowed stems larger than 18mm, flexible reamers larger than those included in kit 4250KIT5 are required. Reamer sizes 18.5mm through 23.5mm (0.5mm increments) can be ordered as SKUs (P/Ns 1811R185, 1811R190, 1811R195, 1811R200, 1811R205, 1811R210, 1811R215, 1811R220, 1811R225, 1811R230 and 1811R235).

Before distal reaming, the appropriate reamer depth should be determined from preoperative templates by adding the lengths of the templated proximal body, the distal stem and an additional 15mm | **TABLE 1.** Before inserting the distal reamers, the flexible ruler should be utilized to mark the necessary depth for stem preparation. The reamers should then be inserted until the mark is at the appropriate depth relative to the tip of the greater trochanter. The guide wire should be utilized with the flexible reamers to ensure proper alignment control.

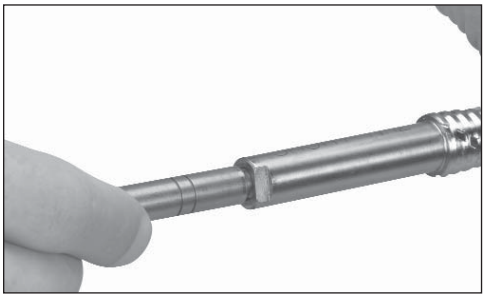


FIGURE 6

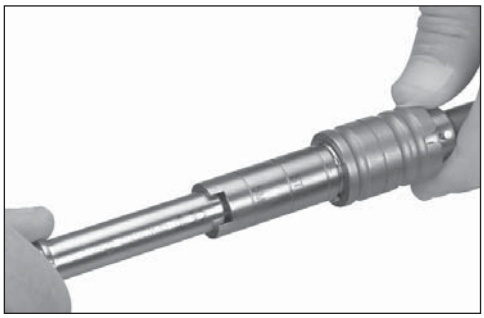


FIGURE 7

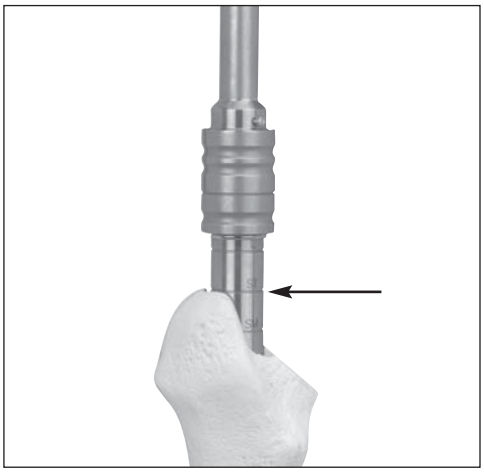


FIGURE 8

DISTAL BROACHES AND TRIALS

NOTE | For bowed stems, femoral bow orientation may be assessed with 9mm smooth curved trials before broaching.

The distal portion of the stem is prepared with the tapered distal broaches. In addition to serving as a broach, the distal broaches act as trials and are utilized to maintain alignment, estimate sizing, and evaluate femoral curvature. Before attaching the distal broach to the distal broach handle, thread the distal broach trial adaptor to the distal broach **| FIGURE 6.** Assemble the distal broach to the distal broach handle by aligning the broach locking collet slot with the peg on the distal broach handle. Lift the locking collet upward and insert the distal broach to the distal broach handle **| FIGURE 7.** The distal broach handle will have three marks that correspond to the proximal body sizes (small, standard, large). Insert the distal broach into the femur until **| FIGURE 8** the appropriate depth mark is aligned with the tip of the greater trochanter. For the x-small modular plasma sprayed proximal body, the distal broach handle should be sunk to 4mm below the "SM" depth mark. Once fully seated, lift the distal broach handle locking collet upward and disengage the distal broach handle from the distal broach.

Distal broaching begins two sizes below the last reamer used and progresses sequentially until cortical contact is achieved. Broaches (to the tips of their teeth) are identical in size to the final implants. Customarily, the final stem implanted is one size larger than the last distal broach used to provide 0.5mm per side of spline bone penetration **| TABLE 2.**

TABLE 2 – RECOMMENDED PRESS-FIT OPTIONS

RECOMMENDED	
.5mm Per Side Press-Fit	
Stem Diameter	Distal Broach
10mm	-
11mm	Size 10
12mm	Size 11
13mm	Size 12
14mm	Size 13
15mm	Size 14
16mm	Size 15
17mm	Size 16
18mm	Size 17
19mm	Size 18
20mm	Size 19
21mm	Size 20
22mm	Size 21

FIGURE 9

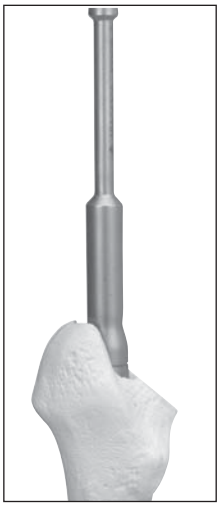


FIGURE 10

JUNCTION REAMER AND PROXIMAL RASP

NOTE | Care should be taken to ensure that the distal broach attachment piece is securely tightened to the distal broach.

After the distal broach is secured in the femur, junction reamers matching the proximal body sizes (standard 1 through large) are provided. Select the appropriate size junction reamer, matching the proximal body size and reamer, and place over the distal broach trial adaptor. Continue junction reaming until the junction reamer has bottomed out **| FIGURES 9 & 10.** The PROFEMUR® system has seven proximal bodies (x-small, small, standard 1 through 4, and large). Proximal rasping should be sequential in nature starting with the smallest size and gradually increasing until the appropriate size is found. Attach the proximal rasp handle to the appropriate proximal rasp by lifting the trigger upward and inserting the locking portion into the oval pocket of the rasp **| FIGURE 11.**

FIGURE 11

The "0" marks on the "S" and "L" scales on the proximal rasp handle approximate the head center of a medium head on a short or long neck, respectively. Proper reaming depth of the proximal reamers is established by inserting the appropriate depth mark 1-3mm below the tip of the greater trochanter.

NOTE | When preparing for the x-small modular proximal body, use the small proximal reamer. The reamer should be inserted until the "S" depth mark is aligned with the tip of the greater trochanter.

NOTE | The depth of the rasp toothed area of the proximal broach should approximate the final location of the roughened surface or plasma sprayed area of the final implant. Only the toothed area of the rasp corresponds to the implant size | FIGURE 12.

FIGURE12

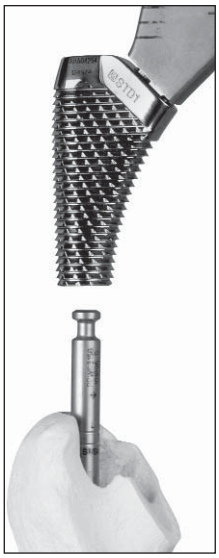


FIGURE 13

FIGURE 14

Place the proximal rasp over the distal broach trial adaptor and utilizing light mallet blows, advance the proximal rasp **| FIGURE 13.**

Attention should be directed toward positioning the rasp into the best bone for optimum fit and fixation. The modular necks will allow this position to be "fine tuned."

If proximal fit is not achieved, remove the proximal rasp, repeat with the next size and continue until the optimal rasp is found. Make sure the distal broach trial adaptor (small/standard and large) is securely tightened to the distal broach. The cannulated design allows proper positioning and alignment for the proximal bodies into the best available bone. Two proximal marks on the distal broach trial adaptor are utilized to ensure proper proximal rasp depth insertion **| FIGURE 14.**

NECK TRIALS

WARNING | METAL NECK TRIALS ARE PROVIDED FOR USE WITH THE PROXIMAL RASPS ONLY.

FIGURE 15

FIGURE 16

Remove the proximal rasp handle. The distal broach trial adaptor piece is now removed and the locking screw inserted and tightened **| FIGURES 15 & 16.**

The locking screw is provided with a split washer to maintain a tight fit between the proximal rasps and distal broaches. Ensure that the split washer is separated before tightening to assure spring tension **| FIGURE 17.**

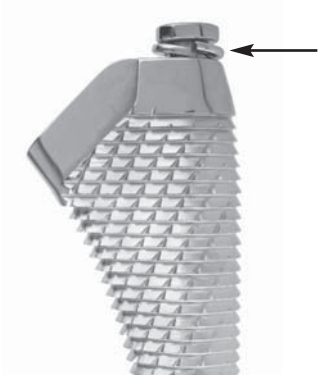


FIGURE 17

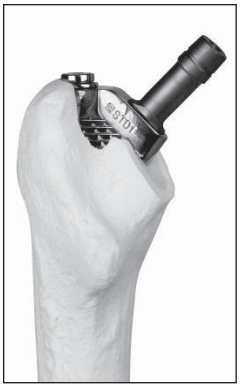


FIGURE 18

FIGURE 19

At this time a trial reduction can be performed by utilizing the metal trial necks. Select the appropriate length trial neck, determined during preoperative templating, If needed, try various combinations of trial necks and trial heads until optimal joint stability and leg length is found **| FIGURES 18 & 19.**

NOTE | The use of metal trial necks is for estimation purposes only. The final and more precise trial reduction of leg length, offset, and anteversion is accomplished by using plastic neck trials with the final implant in place.

After trial reduction and adequate offset and leg length have been evaluated, remove the femoral head and metal trial neck components. Reinsert the proximal rasp handle and remove the proximal rasp and distal broach components **| FIGURE 20.**

WARNING | METAL TRIAL NECKS SHOULD ONLY BE USED WITH RASP TRIALS; NOT THE ACTUAL IMPLANT.

FIGURE 20

EXTRACTION OF BOWED STEM TRIAL

Before extraction of a bowed distal broach, ensure that the locking screw is tightly secured to maintain orientation of the distal broach and proximal rasp. A series of marks on the distal broach and proximal rasp correspond to similar markings on the matching proximal body and distal stem implants. By replicating the orientation of these marks on the final implants, reproduction of the correct bow orientation is possible **| FIGURE 21.**

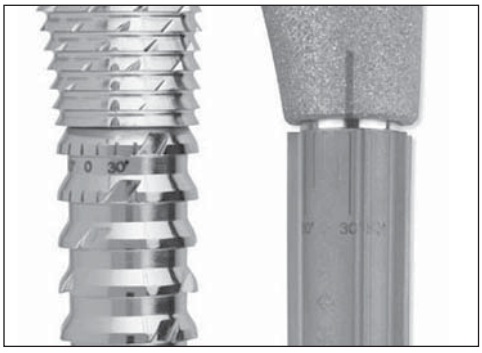


FIGURE 21

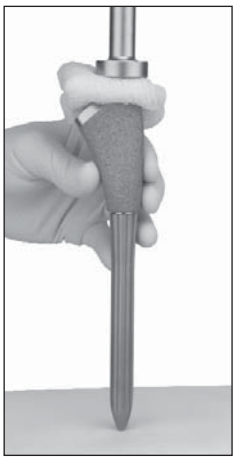


FIGURE 22

FIGURE 23

ASSEMBLY OF IMPLANT

After the appropriate proximal and distal implant components have been selected, they are preliminarily assembled. If implanting a bowed stem, align the appropriate marks on the proximal body and distal stem, ensuring the tapers of the proximal and distal components are clean. Place the two components together with hand pressure. Place the distal stem tip on a padded solid surface. Place a lap sponge over the proximal body and apply firm mallet blows to engage the tapers **| FIGURE 22.** The proximal implant is supplied with a locking screw and proximal hole plug that will be utilized later in the surgical technique.

Assemble the long femoral impactor handle into the proximal hole on the proximal femoral body **| FIGURE 23.** A torsional control bar is supplied and can be inserted into the femoral neck taper region of the proximal body if additional rotational control is required during impaction **| FIGURE 24.**

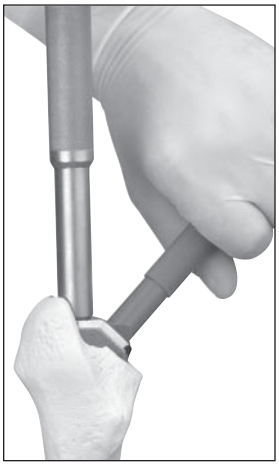


FIGURE 24

FIGURE 25

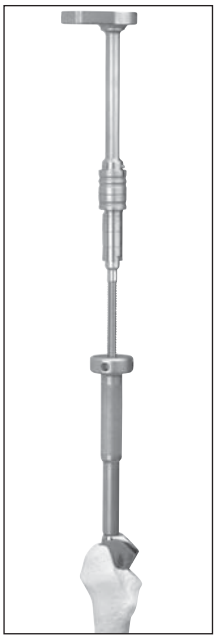


FIGURE 26

If necessary, the proximal body position may be adjusted during impaction through use of the short, cannulated impaction handle. First replace the long impactor handle with the cannulated short impactor handle. Then, insert the threaded separating rod through the hole in the impaction handle. Attach the distal broach handle to the separator rod and turn in a clockwise motion until the proximal and distal tapers are slightly separated **| FIGURES 25 & 26.** Remove the separator rod and cannulated impactor handle by turning in a counter-clockwise motion. Reposition the proximal body in its proper orientation and continue impaction with the long femoral impaction handle. After the implant is fully seated in its proper position, remove the impaction handle and insert the proximal distal locking screw **| FIGURE 27.**

FIGURE 27

FIGURE 28

FIGURE 29

FINAL TRIAL REDUCTION

NOTE | Only the plastic trial necks can be used with the implants.

Select the femoral neck length based on preliminary trial reduction from the use of metal femoral trial necks. Through intraoperative trial reduction, select the appropriate neck configuration and femoral head length that best re-establishes appropriate offset, leg length, and stability for that particular patient **| FIGURES 28 & 29.** Clean and dry the femoral neck pocket on the proximal body. Insert the femoral neck implant into the pocket. Place a lap sponge over the round taper end of the neck and, utilizing firm mallet blows, impact to seat the femoral neck tapers **| FIGURE 30.**

A final trial reduction utilizing a plastic femoral head trial may be done at this time. Assemble the femoral head implant by cleaning the femoral head/neck tapers and seat the femoral head implant utilizing firm mallet blows to the femoral head impactor **| FIGURE 31.** Sealing of the proximal component hole is now accomplished by assembling the hole plug to the proximal body **| FIGURE 32.**

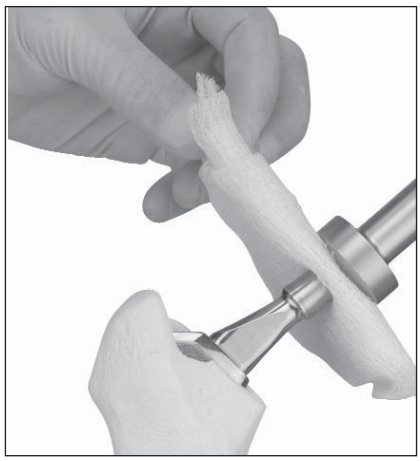


FIGURE 30

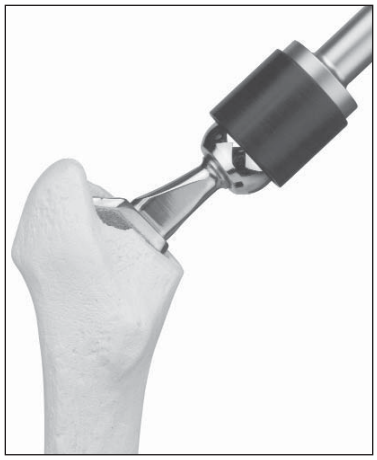


FIGURE 31

FIGURE 32

FIGURE 33

IMPLANT REMOVAL

PROFEMUR® R hip stems may be extracted as one complete construct, or each modular segment may be removed separately.

IMPLANT REMOVAL - ENTIRE STEM

To extract the entire PROFEMUR® R hip stem, first unscrew the proximal body hole plug with the screwdriver. Next, screw the long impactor handle into the top of the proximal body. Utilizing a mallet or the slide hammer, extract the hip stem.

IMPLANT REMOVAL - FEMORAL HEAD

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.

FIGURE 34

IMPLANT REMOVAL - FEMORAL NECK

With the femoral head removed, thread the adaptor over the round taper end of the modular neck **| FIGURE 33.** Place the head/neck extractor over the adaptor and modular neck **| FIGURE 34**, 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 **| FIGURE 35.**

NOTE | 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 to the hex end of the extractor and rotate clockwise until the neck taper disengages **| FIGURE 36.** The Tommy bar can be inserted into the end of the spanner handle for even greater leverage **| FIGURE 37.**

FIGURE 35

FIGURE 36

FIGURE 37

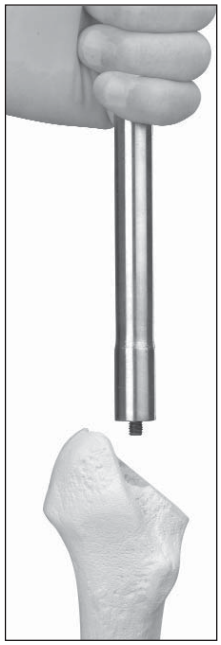


FIGURE 38

FIGURE 39

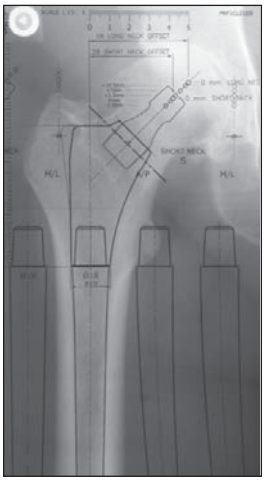
IMPLANT REMOVAL - PROXIMAL BODY

Utilizing the screwdriver, remove the proximal body hole plug and loosen the proximal/distal locking screw. Thread the long handle impactor into the proximal body. Using a mallet or slide hammer, extract the proximal body.

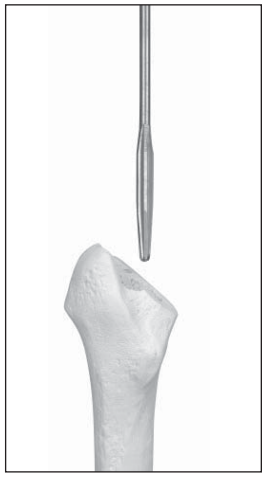
IMPLANT REMOVAL - DISTAL STEM

Thread the distal stem extractor onto the distal stem | **FIGURE 38.** Using the slide hammer, extract the distal stem | **FIGURE 39.**

APPENDIX A | ABBREVIATED SURGICAL TECHNIQUE



STEP 1 | X-ray templating of lateral and A/P view.



STEP 2 | Find canal axis.

STEP 3 | Broach distally until cortical contact is achieved.

STEP 4 | Proximally ream until appropriate mark is slightly below the greater trochanter.

STEP 5 | Broach up from the smallest size. Broach teeth approximate implant.

STEP 6 | Trial with metal necks to preliminarily determine neck length.

STEP 7 | Assemble implant on solid surface.

STEP 8 | Insert stem with long impactor handle.

STEP 9 | Insert stem locking screw (must be done before neck insertion).

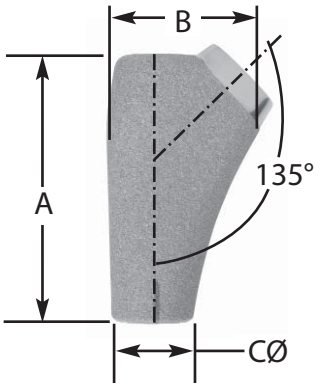
STEP 10 | Trial using plastic necks and heads.

STEP 11 | Seat neck and head implants.

STEP 12 | Insert hole plug.

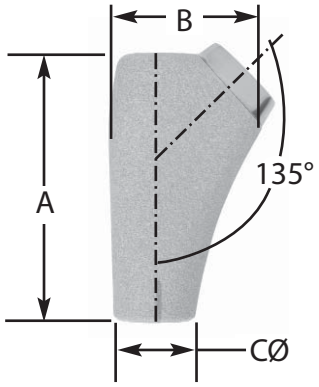
APPENDIX B | REFERENCE CHARTS

PROXIMAL BODIES | Grit Blast



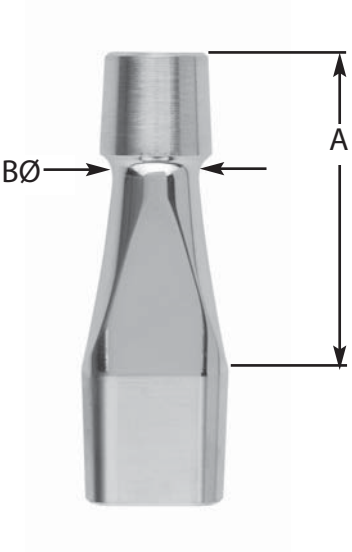
Size	A	B	CØ	CATALOG #
X-Small Monoblock	54	31	18	PPW38058
Small	54	34	18	PPW39102
Standard 1	67	37	19	PPW39104
Standard 2	67	39	20.5	PPW39106
Standard 3	67	42	22	PPW39108
Standard 4	67	44	23.5	PPW39110
Large	80	47	25	PPW39112

PROXIMAL BODIES | Plasma Spray



Size	A	B	CØ	CATALOG #
X-Small Monoblock	54	31.5	18.6	PPW38358
X-Small	50	53	18.6	PPW38354
Small	54	34	18.6	PPW38360
Standard 1	67	37	19.6	PPW38361
Standard 2	67	39	21.1	PPW38362
Standard 3	67	42	22.6	PPW38363
Standard 4	67	44	24.1	PPW38364
Large	80	47	25.6	PPW38365

Provide .25mm press-fit per side.



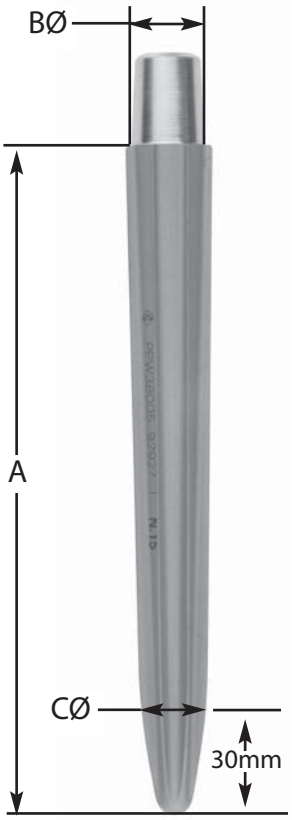
DIMENSIONAL CHART | FEMORAL NECKS (mm)

TYPE	A	BØ	CATALOG #
Neutral			
Short	28	10.6	PHA01202
Long	38.5	10.6	PHA01204
Varus/Valgus			
Short	27	10.6	PHA01252
Long	38	10.6	PHA01254
Ante/Retro 8 Degree			
Short	28	10.6	PHA01232
Long	38.5	10.6	PHA01234
Ante/Retro 15 Degree			
Short	28	10.6	PHA01242
Long	38.5	10.6	PHA01244
Ante/Retro - Varus/Valgus 1			
Short	28	10.6	PHA01222
Long	38.5	10.6	PHA01224
Ante/Retro - Varus/Valgus 2			
Short	28	10.6	PHA01212
Long	38.5	10.6	PHA01214

DIMENSIONAL CHART | STEM EXTENSIONS (mm)

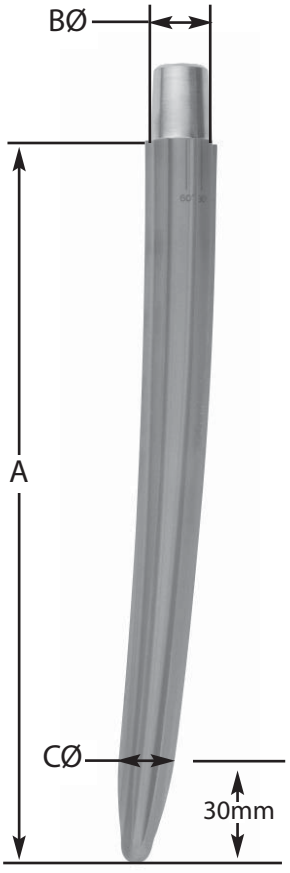
CATALOG #	LENGTH	OUTER Ø
PPW00140	26	19
PPW00141	26	21
PPW00142	26	23
PPW00144	52	19
PPW00148*	26	19

***FOR USE WITH X-SMALL MONOBLOCK PROXIMAL BODIES**



STEMS | Tapered Splined

A	BØ	CØ	TYPE	CATALOG #
135	18	10	Straight	PPW38000
135	18	11	Straight	PPW38001
135	18	12	Straight	PPW38002
135	18	13	Straight	PPW38003
135	18	14	Straight	PPW38004
135	19	15	Straight	PPW38005
135	20	16	Straight	PPW38006
135	21	17	Straight	PPW38007
135	22	18	Straight	PPW38008
135	23	19	Straight	PPW38009
135	24	20	Straight	PPW38010
135	25	21	Straight	PPW38011
135	26	22	Straight	PPW38012



STEMS | Tapered Splined

A	BØ	CØ	TYPE	CATALOG #
175	18	10	Bowed	PPW38020
175	18	11	Bowed	PPW38021
175	18	12	Bowed	PPW38022
175	18	13	Bowed	PPW38023
175	18	14	Bowed	PPW38024
175	19	15	Bowed	PPW38025
175	20	16	Bowed	PPW38026
175	21	17	Bowed	PPW38027
175	22	18	Bowed	PPW38028
175	23	19	Bowed	PPW38029
175	24	20	Bowed	PPW38030
175	25	21	Bowed	PPW38031
175	26	22	Bowed	PPW38032
215	19	10	Bowed	PPW38040
215	19	11	Bowed	PPW38041
215	19	12	Bowed	PPW38042
215	19	13	Bowed	PPW38043
215	19	14	Bowed	PPW38044
215	20	15	Bowed	PPW38045
215	21	16	Bowed	PPW38046
215	22	17	Bowed	PPW38047
215	23	18	Bowed	PPW38048
215	24	19	Bowed	PPW38049
215	25	20	Bowed	PPW38050
215	26	21	Bowed	PPW38051
215	27	22	Bowed	PPW38052

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