

**PROFEMUR<sup>®</sup>** Total Hip System



TECHNICAL MONOGRAPH



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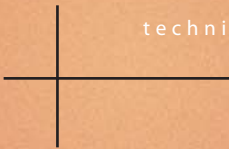
**PROFEMUR<sup>®</sup>**

total hip SYSTEM

PERFORMANCE CHARACTERISTICS

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technical monograph



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# PROFEMUR®

total hip SYSTEM

## PERFORMANCE CHARACTERISTICS OF THE PROFEMUR TOTAL HIP SYSTEM

### introduction

As the total hip replacement market exceeds one billion dollars in sales, primary and revision stem designs have migrated towards increased modularity. The major reason for the interest in modular stems is the necessity for independent proximal and distal fit and fill. In addition, some clinicians believe that the shape of the prosthesis itself plays a critical role in the distribution of loads within the femur and therefore dictates whether stress shielding occurs.

Modularity has also entered prominently into the revision hip implant market primarily due to improved joint stability in terms of offset, version, and restoration of leg length. Another advantage of modularity is the ability to restore the femoral head center while retaining a well-fixed acetabular shell. Depending on the particular revision implant this may or may not be possible and a well-fixed shell will need to be revised. Most of the modular designs have proximal and distal components that are ideal for addressing proximal/distal mismatches within the revision femur. These types of implants also allow the ability to adjust the version of the proximal body independently of the distal stem. Most of the proximal components in modular revision systems have a fixed neck and therefore typically are offered with a choice of standard or extended offset to properly tension the joint. Proximal components of various lengths are sometimes included within a system to address leg length issues. For a fixed neck system to be able to address leg length, version, joint tension, and conserve a well-fixed acetabular shell while fitting patients of various sizes it will have many components, i.e. large inventory. The modular PROFEMUR® Hip System offers both the advantages of modularity with the full choice of primary and revision components.



### DESIGN HISTORY

The PROFEMUR® Revision System gets its roots from Europe where it has been successfully used since the early 1990s in over 4,000 implantations.

The original PROFEMUR® Hip is a modular prosthesis,

manufactured from Ti6Al4V comprising of four principal parts:

- Light corundum surface texture (2 Ra), Wagner style, tapered distal stem with cutting flutes for the diaphyseal region
- Rough corundumized surface texture (6 Ra) proximal body component for support in the metaphyseal region
- Modular neck
- Head



In addition to the original PROFEMUR® Components, porous coated stems and bodies, as well as cylindrically shaped splined stems have been added to the product offering. These additions also manufactured from Ti6Al4V and include the following features:

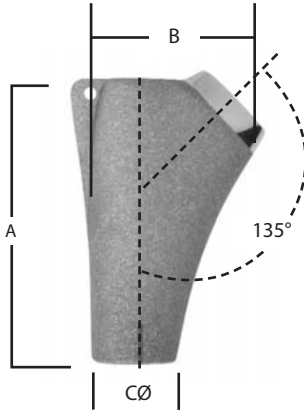
- Light surface texture (2 Ra), cylindrical, distal stem with cutting flutes and a flexible slot for the diaphyseal region
- Pure titanium extensively plasma sprayed, cylindrical, distal stem
- Pure titanium plasma sprayed proximal component for support in the metaphyseal region

### CLINICAL HISTORY

The modular neck used with the PROFEMUR® Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the PROFEMUR® Hip. None of the necks has experienced a clinical failure since their inception.

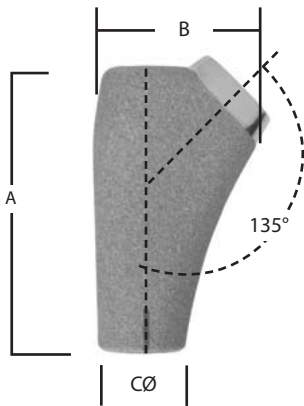
<sup>1</sup> Kohler, Kostler, Willert- in 1997 shared their clinical experience with 80+ revision cases implanted since 1992. The follow up period ranged between 6 months and 54 months for 67 patients with 69 PROFEMUR® implants. Of the stems being revised using PROFEMUR® Implants, 31 were cemented and 38 were noncemented. The mean Harris Hip Scores improved from 44.6 to 75 points and radiographic examination showed good bone integration and formation.

<sup>2</sup> Masse *et al*- in 1996 related their 2.5 year clinical results with 134 cases. The mean Harris Hip Scores improved an average of 34 points. It was determined that the medium (175mm) distal stem which was originally straight, should be offered bowed. To reduce the chance for splitting the femur, it was noted that the anterior and posterior splines should be removed from the bowed stems. Another recommendation was that the stems be offered in 1mm increments instead of 2mm. It was also learned from this research that 2 smaller proximal bodies (extra small and small) should be added to the system.



**PROXIMAL BODIES | GRIT BLAST**

SIZE	A	B	CØ
X-Small	54	31	18
Small	54	34	18
Standard 1	67	37	19
Standard 2	67	39	20.5
Standard 3	67	42	22
Standard 4	67	44	23.5
Large	80	47	25



**PROXIMAL BODIES | PLASMA SPRAY**

SIZE	A	B	CØ
X-Small	54	31	18.6
Small	54	34	18.6
Standard 1	67	37	19.6
Standard 2	67	39	21.1
Standard 3	67	42	22.6
Standard 4	67	44	24.1
Large	80	47	25.6

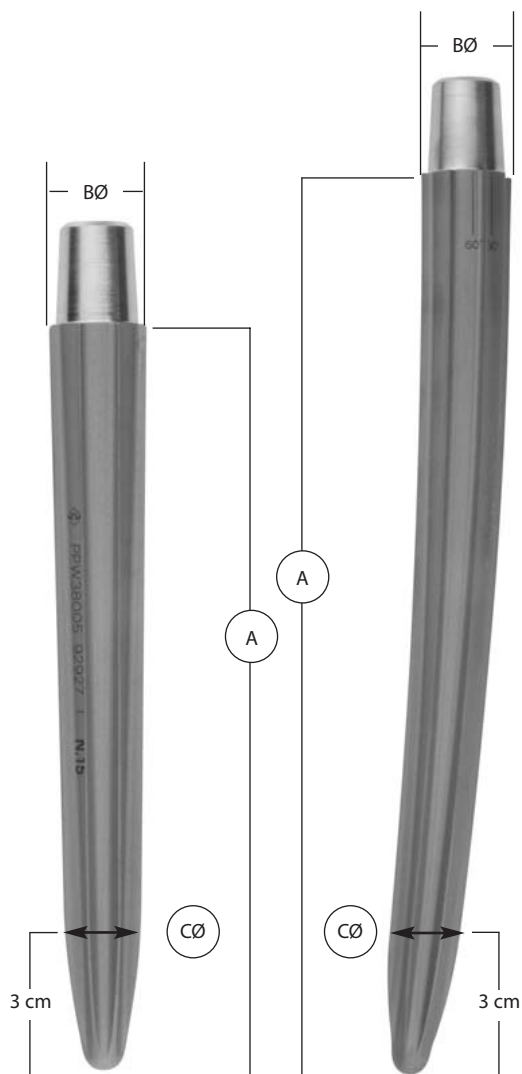
**COMPONENT DESIGN FEATURES**

**- PROXIMAL BODY**

Following several years of clinical evaluation, a more encompassing range of PROFEMUR® proximal bodies was produced in 1996. A fixed neck, extra small component was added to the range, suitable for all cases when it is necessary to adopt a transfemoral approach and also for dysplasia. The small, standard 1, 2, 3, 4 and large components all accept the modular necks. The surface roughness is 236 Ra (microinches, 6 Ra in micrometers) via corundum treatment in order to better assist secondary osteoapposition. A thin lateral wing assists in stabilizing the body torsionally and, when necessary, allows the consolidation of the trochanteric fragments or muscles with the implant. The lateral A/P thicknesses incorporate an ellipsoidal shape for minimizing the potential for excessive stress on the bone when inserting the component.

The newly added plasma spray coated bodies are available in the same sizes and have a 500 micron thick coating of pure titanium plasma spray. This coating thickness provides a 0.25mm scratch fit compared to the line to line fit of the grit blasted proximal bodies. The plasma spray coated proximal bodies also differ from the grit blasted bodies in that they do not have the thin lateral wing. The polished collar above the oblong taper housing for the modular necks varies in length with size; thus allowing reproduction of the correct articular offset. This is most important to produce a stable and successful hip joint replacement, and should be as close as possible to that of the other limb. Studies on more than one thousand femurs dictated the optimal correlation between the dimensions of the proximal femur and the neck length.

All of the proximal bodies are connected to the distal stems via a Morse taper, which is well proven and gave excellent results in torsional resistance tests. The use of a fixation screw offers further security. The proximal body also features a threaded protective cap, which covers the fixation screw thus keeping the screw and shaft clean while simplifying extraction and separation should it be required. The modularity of these components allows easy torsional correction of the proximal body without compromising distal stability.

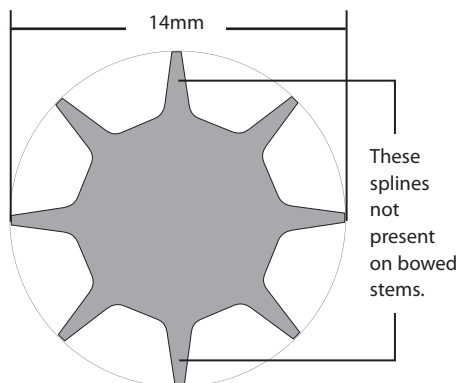


### COMPONENT DESIGN FEATURES

#### - TAPERED STEM

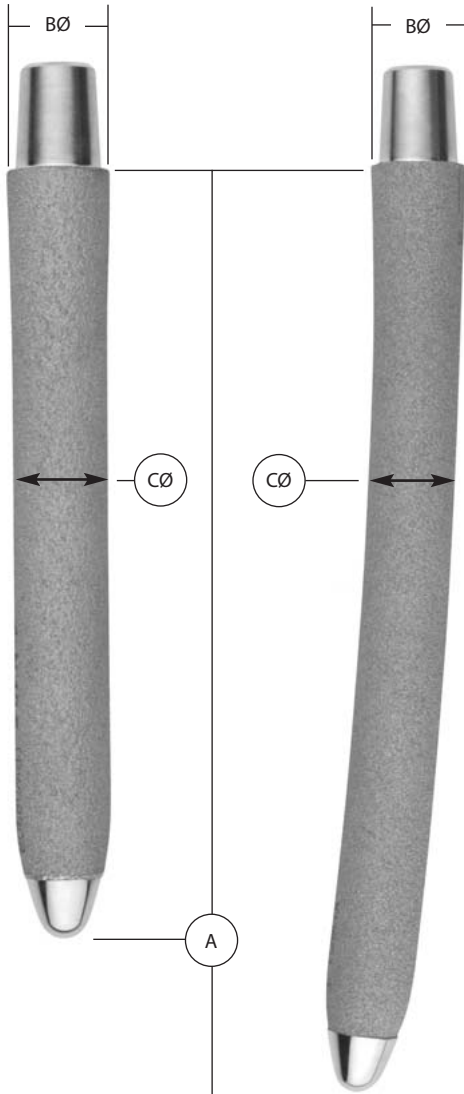
The tapered stems are offered in 3 lengths: 135mm straight, 175mm bowed and 215mm bowed and increase in diameter by 1mm increments. Size increments of 1mm allow greater sensitivity and better choice of spline penetration (0mm, 1mm, or 2mm). The radius of curvature for the bowed stems was chosen following studies made on over one thousand femurs. Eight radially arranged splines extend along the length of the straight stems. On the bowed stems, to ease implant insertion and minimize fracture risk, the splines at the bow's concavity and convexity are removed leaving 6 splines. The splines extend along nearly the full length of the stem, making insertion and, if needed, extraction smoother. Spline height is proportional to the diameter of the stem and decreases from its maximum height distally to its minimum proximally, resulting in good fixation and rotational stability. Also, a range of precise broaches of the same dimensions as the stem is offered. They permit an exact preparation of the diaphysis, i.e. a size 12 broach has the same profile as the size 12 implant. It is the conical profile of the tapered stem that reduces the potential for distal tip impingement and provides the proximal loading necessary to reduce stress shielding. Of the tapered type of stem geometry, Wagner and Wagner 3 with their experience of over 20 years state the following:

“ In the case of conical fixation, the mechanical transmission of force varies with the diameter of the stem: the weight bearing surface of a cone in relation to its length is greater where the stem has a larger diameter than at the tip of the stem where it is smaller. Therefore, for geometrical reasons, the conical fixation of the stem results in a transmission of force that is predominately proximal and avoids proximal stress protection.”



TAPERED STEM CROSS SECTION  
Size 14 Stem

STEMS   Tapered Splined				STEMS   Tapered Splined				STEMS   Tapered Splined			
A	BØ	CØ	TYPE	A	BØ	CØ	TYPE	A	BØ	CØ	TYPE
135	18	10	Straight	175	18	10	Bowed	215	19	10	Bowed
135	18	11	Straight	175	18	11	Bowed	215	19	11	Bowed
135	18	12	Straight	175	18	12	Bowed	215	19	12	Bowed
135	18	13	Straight	175	18	13	Bowed	215	19	13	Bowed
135	18	14	Straight	175	18	14	Bowed	215	19	14	Bowed
135	19	15	Straight	175	19	15	Bowed	215	20	15	Bowed
135	20	16	Straight	175	20	16	Bowed	215	21	16	Bowed
135	21	17	Straight	175	21	17	Bowed	215	22	17	Bowed
135	22	18	Straight	175	22	18	Bowed	215	23	18	Bowed
135	23	19	Straight	175	23	19	Bowed	215	24	19	Bowed
135	24	20	Straight	175	24	20	Bowed	215	25	20	Bowed
135	25	21	Straight	175	25	21	Bowed	215	26	21	Bowed
135	26	22	Straight	175	26	22	Bowed	215	27	22	Bowed



### COMPONENT DESIGN FEATURES

#### - CYLINDRICAL PLASMA SPRAYED STEM

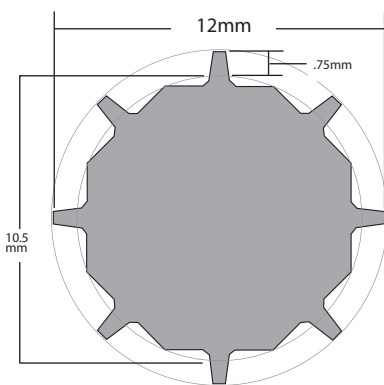
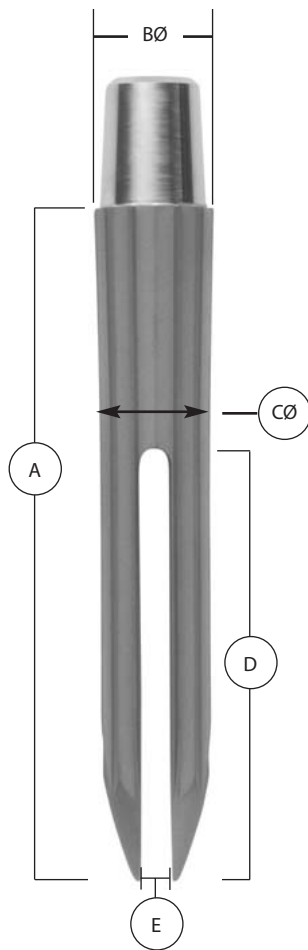
The cylindrical fully coated stems are offered in 3 lengths: 115mm straight, 135mm straight and 175mm bowed. These stems feature the same Morse taper and accept the same securing screw for secondary fixation as the tapered distal stems. The plasma spray coating is of pure titanium and is applied to a thickness of 300 microns to allow line to line fit within the diaphysis when prepared with the same diameter reamer. The stems are fully coated except for the bullet shaped, polished distal tip that serves to reduce the possibility of cortex impingement which in turn can lead to thigh pain. Like the tapered stem of the same length, the 175mm bowed stem incorporates the same radius of curvature. All of the plasma sprayed stems range in size from 10.5 to 22.5 in 1.5mm increments

**STEMS** Cylindrical Plasma Sprayed

A	BØ	CØ	TYPE
115	18	10.5	Straight
115	18	12	Straight
115	18	13.5	Straight
115	18	15	Straight
115	18	16.5	Straight
115	18	18	Straight
115	19.5	19.5	Straight
115	21	21	Straight
115	22.5	22.5	Straight
135	18	10.5	Straight
135	18	12	Straight
135	18	13.5	Straight
135	18	15	Straight
135	18	16.5	Straight
135	18	18	Straight
135	19.5	19.5	Straight
135	21	21	Straight
135	22.5	22.5	Straight

**STEMS** Cylindrical Plasma Sprayed

A	BØ	CØ	TYPE
175	18	10.5	Bowed
175	18	12	Bowed
175	18	13.5	Bowed
175	18	15	Bowed
175	18	16.5	Bowed
175	18	18	Bowed
175	19.5	19.5	Bowed
175	21	21	Bowed
175	22.5	22.5	Bowed



**CYLINDRICAL STEM CROSS SECTION**  
Size 12 Stem

## COMPONENT DESIGN FEATURES

### - CYLINDRICAL SPLINED AND SLOTTED STEM

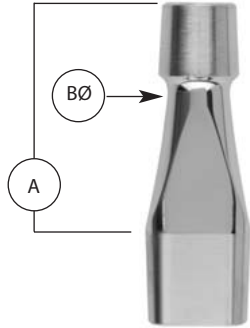
The cylindrical splined and slotted stem features the same Morse taper and accepts the same securing screw for secondary fixation as the tapered distal stems. The stems are offered in 95, 115 and 135mm straight lengths. The splined and fluted stem surface finish is identical to the tapered stem at 2 microns Ra for proven osteoapposition.<sup>4</sup> The spline geometry is nearly identical to the tapered stem spline; however, because the stem is cylindrical, the spline height is constant along its length. The cross sectional geometry of the stem allows for 0.75mm of spline penetration into the endosteal bone when under-reamed by one size, i.e. reaming to 12.0mm for a 13.5mm implant stem. This is due to the profile of the implant stem, inclusive of the splines, being equal to diameter of the same size cylindrical reamer. The fluted slotted stem features a distal slot that adds to the flexibility of the stem and minimizes the incidence of thigh pain. As stem diameter increases so does the slot width and length so that the force required to close the ends of the slot is linearly proportional to the rigidity of the stem. To further reduce the risk of thigh pain, the distal tip is bullet shaped. As with the plasma sprayed cylindrical stems, the splined and slotted stems are offered in 1.5mm increments ranging from 10.5 to 22.5mm.

#### DISTAL STEMS | Cylindrical Splined and Slotted

A	BØ	CØ	D	E	TYPE
95	18	10.5	50	2.3	Straight
95	18	12	51	2.8	Straight
95	18	13.5	54	3.3	Straight
95	18	15	57	3.8	Straight
95	18	16.5	61	4.3	Straight
95	18	18	63	4.8	Straight
95	19.5	19.5	66	5.5	Straight
95	21	21	69	5.5	Straight
95	22.5	22.5	72	6.4	Straight
115	18	10.5	50	2.3	Straight
115	18	12	51	2.8	Straight
115	18	13.5	54	3.3	Straight
115	18	15	57	3.8	Straight

#### DISTAL STEMS | Cylindrical Splined and Slotted

A	BØ	CØ	D	E	TYPE
115	18	16.5	61	4.3	Straight
115	18	18	63	4.8	Straight
115	19.5	19.5	66	5.5	Straight
115	21	21	69	5.5	Straight
115	22.5	22.5	72	6.4	Straight
135	18	10.5	50	2.3	Straight
135	18	12	51	2.8	Straight
135	18	13.5	54	3.3	Straight
135	18	15	57	3.8	Straight
135	18	16.5	61	4.3	Straight
135	18	18	63	4.8	Straight
135	19.5	19.5	66	5.5	Straight
135	21	21	69	5.5	Straight
135	22.5	22.5	72	6.4	Straight



**FEMORAL NECKS**

TYPE	A	BØ	CATALOG #
<b>NEUTRAL</b>			
Short	28	10.6	PHA01202
Long	38.5	10.6	PHA01204
<b>VARUS/VALGUS 8 DEGREE</b>			
Short	27	10.6	PHA01252
Long	38	10.6	PHA01254
<b>ANTE/RETRO 8 DEGREE</b>			
Short	28	10.6	PHA01232
Long	38.5	10.6	PHA01234
<b>ANTE/RETRO 15 DEGREE</b>			
Short	28	10.6	PHA01242
Long	38.5	10.6	PHA01244
<b>4 DEGREE ANTE/RETRO - 6 DEGREE VARUS/VALGUS 1</b>			
Short	28	10.6	PHA01222
Long	38.5	10.6	PHA01224
<b>4 DEGREE ANTE/RETRO - 6 DEGREE VARUS/VALGUS 2</b>			
Short	28	10.6	PHA01212
Long	38.5	10.6	PHA01214

**COMPONENT DESIGN FEATURES**

– MODULAR NECKS

The modular neck system, designed by Cremascoli in 1985 (U.S. Patent # 4,957,510), has now been successfully implanted in OVER 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests has proven that the coupling between the modular neck and femoral implant guarantees:

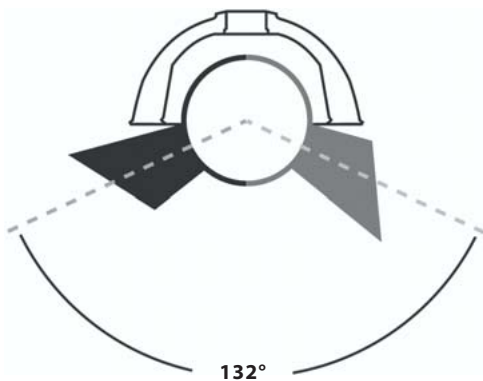
- Structural reliability
- Absence of significant micromovement
- Absence of fretting corrosion

These excellent characteristics are obtained due to the particular geometry of the coupling. The base of the neck and the neck housing in the femoral implant have a patented oblong, conical profile which allows excellent stability under stress and the absence of all significant movement. The surface of the modular neck is finely machined to create spiral grooving. The crest of these grooves deforms when the neck is inserted into the neck housing ensuring contact and elimination of micromotion. The necks are made from titanium alloy (Ti6Al4V) which is well proven with suitable mechanical properties, very good biocompatibility, and excellent resistance to corrosion.

The modular neck system allows the surgeon to correct leg length and offset intraoperatively. The surgeon may choose between six interchangeable necks available in two lengths. Further adjustments may be made with the choice of femoral head neck lengths. The neck and head are connected via a standard 12/14 Morse taper.

	HEAD -3.5	0	+3.5	+7	+10.5
<b>RANGE OF MOTION</b>	<b>132°</b>	<b>132°</b>	<b>132°</b>	<b>96°</b>	<b>96°</b>

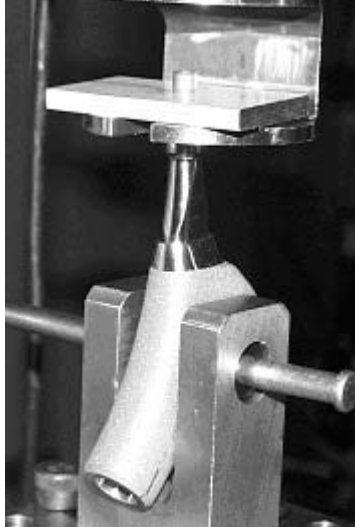
**RANGE OF MOTION USING LINEAGE™ ACETABULAR Shell and 0° Liner**



**RANGE OF MOTION IN DEGREES**  
28 mm by 0mm Head Length



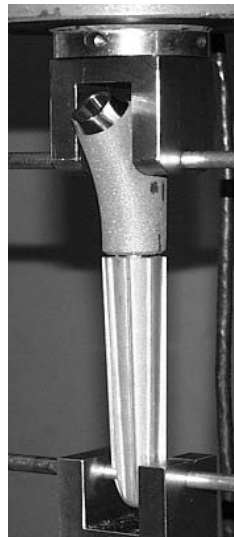
Ref. A Data on file at Wright Medical Technology, Inc.  
 Ref. B www.biomet.com, 2001  
 Ref. C www.ceramic-hip.com, 2001  
 Ref. D VerSys™ Design Rationale. 1996 Zimmer, Inc. publication



TAPER DISTRACTION



TAPER ASSEMBLY

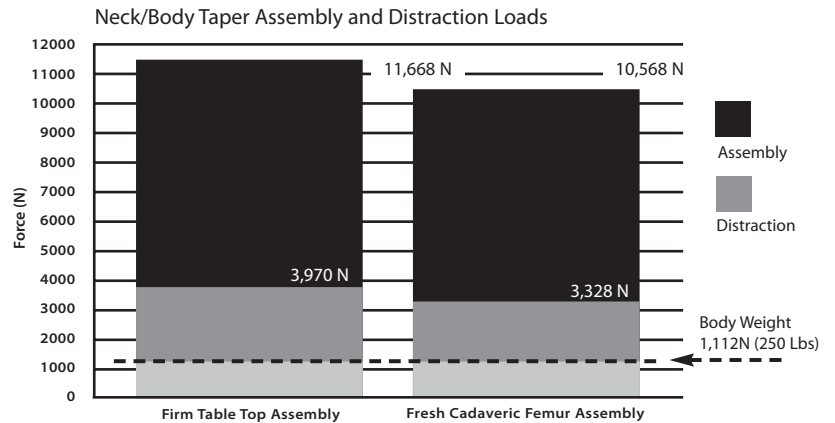


TAPER DISTRACTION

## TESTING

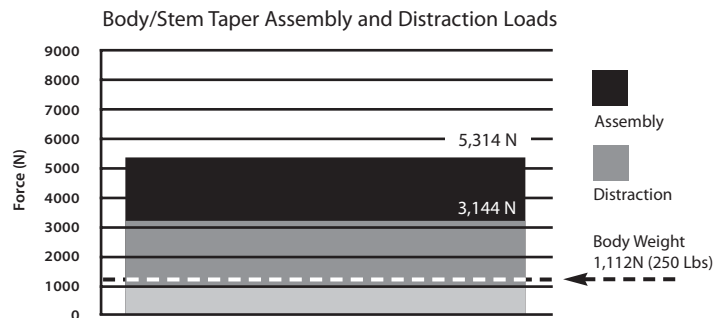
### - NECK/BODY TAPER ASSEMBLY AND DISTRACTION<sup>5</sup>

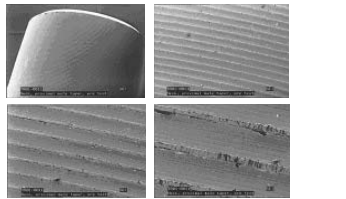
Six couplings were tested. A coupling consisted of a large proximal body and a long, straight modular neck. Assembly for 4 of the couplings occurred by 3 firm surgical mallet blows of the components on a firm tabletop. Assembly of the 2 remaining couples occurred in a fresh cadaver femur. The average assembly force was 11,668 N for the table assembly and 10,568 N for the femoral assembly. The average distraction force was 3,970 N for the table-assembled couples and 3,328 N for the couples assembled in the femur (both are nearly 3 times a 250 lb. body weight). This test was a static test. The distraction values are generally higher once the implant is subjected to axial loading, i.e. walking.



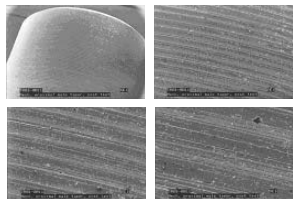
### BODY/STEM TAPER ASSEMBLY AND DISTRACTION<sup>6</sup>

Six couplings were tested. A coupling consisted of a large proximal body and a short 22mm tapered stem. Assembly occurred by 3 firm surgical mallet blows of the components on a wooden tabletop. The average assembly force was 5,314 N and the average distraction force was 3144 N (nearly 3 times a 250 lb. body weight). This test was a static test. The distraction values are generally higher once the implant is subjected to axial loading, i.e. walking.

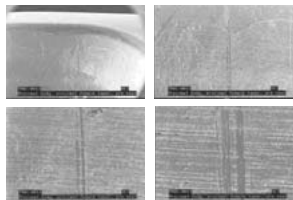




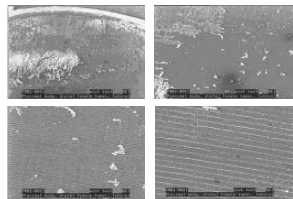
**BEFORE TESTING** | Neck and Head Taper



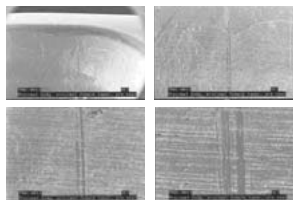
**AFTER TESTING** | Neck and Head Taper



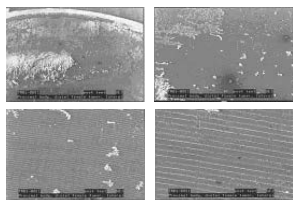
**BEFORE TESTING** | Body and Neck Taper



**AFTER TESTING** | Body and Neck Taper



**BEFORE TESTING** | Modular Neck/Body Taper

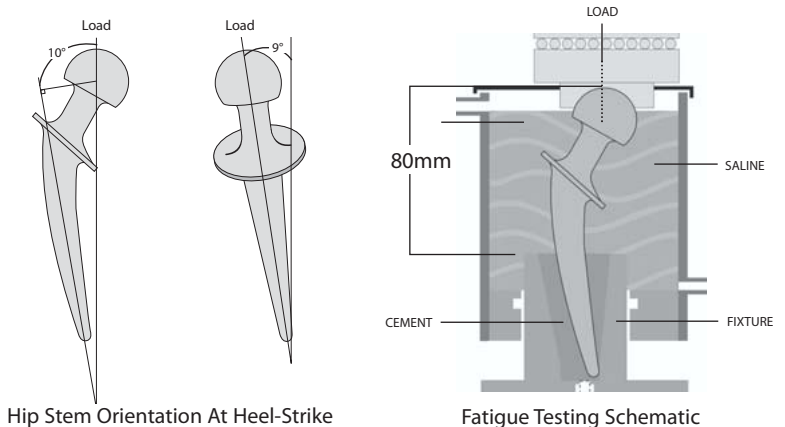


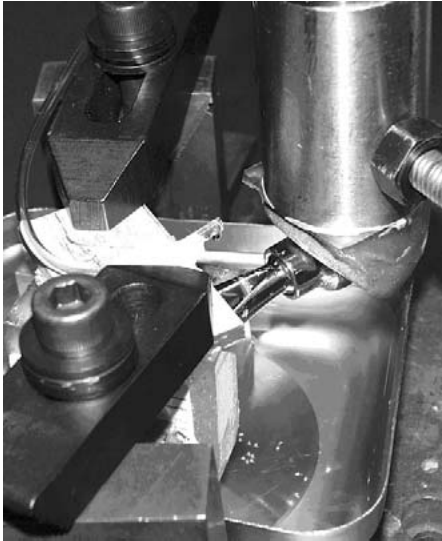
**AFTER TESTING** | Modular Neck/Body Taper

10/9 FATIGUE TESTING<sup>7,8</sup>

Fatigue testing was performed at the WMT testing facility per ISO 7206/4, and 7206/8, on “the worst-case” combination of components (WMT 28mm XXL head, small body, 10 mm stem, and long varus/valgus neck). Using the ISO guidelines, the assembled components were fixtured in the potting media which left the distal stem taper connection exposed. The components were oriented at 10 degrees adduction and 9 degrees of flexion within an environmental chamber containing saline solution. This orientation represents the heel-strike phase of the gait cycle. One test utilized the rough corundumized proximal body and tapered stem of the original PROFEMUR® System and another test involved the new plasma sprayed proximal body and plasma sprayed cylindrical stem. In both tests, six samples passed the testing requirements with no failures after 5 million cycles at a maximum load of 2,300 N (over 2 times a 250 lbs. body weight). After completion of the fatigue testing, the assembled components were checked and no visible signs of taper fretting were found around any of the modular connections or within the environmental chamber.

Taper connections were photographed by scanning electron microscopy (SEM) before and after testing. No evidence of excessive fretting or corrosion was observed. There were no particulate metallic debris noted when the components were separated or during cleaning in preparation for the SEM. Areas that were stained white were identified to be residual salts remaining from the fatigue test fluid. The neck/body taper surface of the modular neck exhibited areas of metal deformation, longitudinal smearing and scratching following testing especially on the lateral aspect. This area corresponds to the approximate area of highest bending stresses. The modular neck also had a similar region on the taper surface of the head/neck taper corresponding to the area of highest bending stress. Each of the pictures to the left show a particular feature in 4 increasing magnifications.





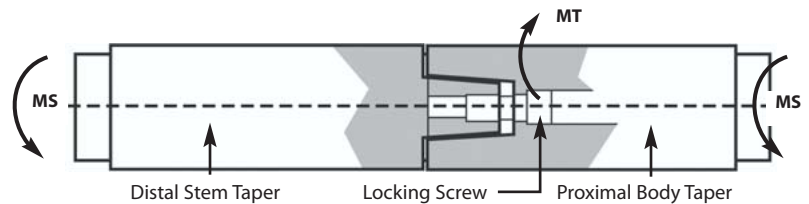
DEEP FLEXION FATIGUE TESTING

DEEP FLEXION FATIGUE TESTING<sup>9</sup>

This test was performed to examine the modular neck taper’s structural integrity in the “worst case” orientation of a person rising from deep flexion, i.e. rising from a chair. Three small proximal bodies, six long varus/valgus necks and six xxl 28mm WMT femoral heads were assembled with 3 blows of a surgical mallet. This combination of implants allows the largest bending moment, as well as torsion, and represents the “worst-case” scenario for implant selection. The assembled implants were fixtured within the testing frame such that the orientation mimicked that of a sitting person’s proximal femur. A maximum load 2,300 N load (over 2 times a 250 lbs. body weight) was applied at a ninety degree angle with respect to the floor at 2 Hz for one million cycles. One million cycles is equivalent to rising from a chair fifty times a day for over fifty-four years. None of the three specimens failed and the neck remained fixed within the proximal body’s taper housing.

BODY/STEM TAPER TORSIONAL RESISTANCE<sup>10</sup>

In order to assess the torsional resistance of the proximal body and distal stem taper torsional resistance, 10 couplings were made. A coupling is the component with the male conic taper, a component with the female conic taper, and a securing screw; all identical to the same features on the implant. Torque input to the screwdriver (MT) that tightened the securing screw varied from 5 to 12 Nm. The slipping torque of the couplings (MS) responded linearly in a range of 22 to 55 Nm. The torque applied to a prosthetic stem can, during some motor acts, reach 20 Nm. The presence of axial loading, as would be the case in vivo, would only increase the slipping torque. This testing was performed without axial loading.



TAPER TORSIONAL RESISTANCE SCHEMATIC



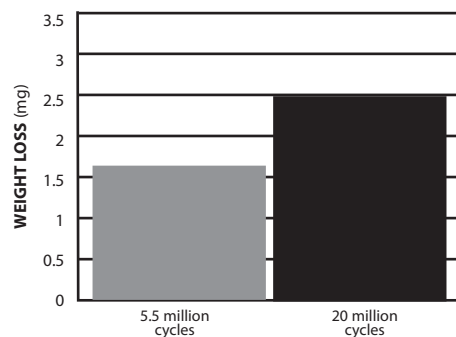
**MODULAR NECK AFTER COMPRESSIVE YIELD**

#### ENDURANCE STRENGTH AND YIELD STRENGTH OF THE MODULAR NECK <sup>11</sup>

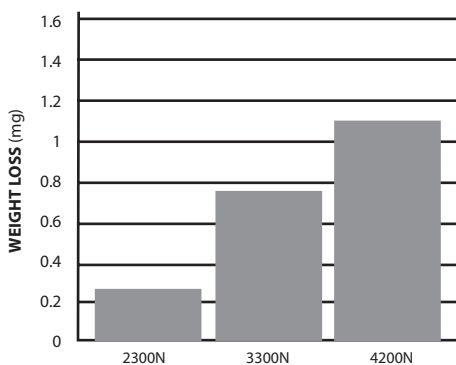
The endurance strength of the modular neck was determined with the mating femoral implant oriented at 10 degrees adduction and 0° of flexion (ISO 7206/6). The endurance strength was estimated to be 4,900 N (over 4 times a 250 lbs. body weight). Endurance Strength is defined as the maximum force applied such that the modular neck could withstand 5.5 million cycles. Static testing found the average compressive yield load measured for each of the different modular necks to be 14,900 N (3,350 lbs.).

#### FRETTING ANALYSIS OF THE NECK TAPER – WEIGHT LOSS

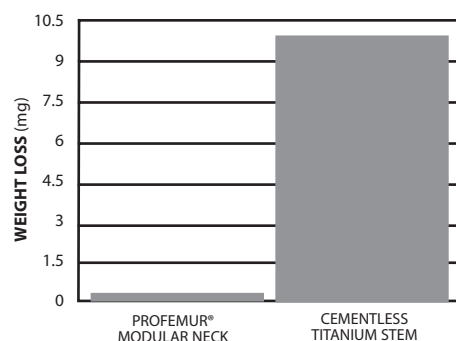
A cyclic loading test<sup>12</sup> was performed on two types of stems. The stems differed in their taper size. One set of implants tested use the same modular necks as PROFEMUR®. The other set of implants has a smaller size neck taper. The tests were conducted in 3 different environments: FeCl<sub>3</sub>, buffered Ringer's solution, and air. Load was applied at 2 Hz ranging from 200 to 2,100 N (3x 160 lbs. body weight) for one million cycles, which approximates the yearly loading cycle. Both taper sizes were found to be corrosion resistant, however there were signs of mechanical wear which differed widely in extent between the 2 sizes. The prototype necks in the acidic FeCl<sub>3</sub> lost an amount of material “in the range of 100 to 200 mg.” The GSP taper necks (same as on the PROFEMUR® hip) “showed a material loss in the range of 0 – 1mg. A sound taper design is essential in minimizing both corrosion and mechanical wear.”<sup>12</sup>



**FIGURE 1** | Fatigue generated titanium production by weight PROFEMUR® Modular Neck loaded to 3300N



**FIGURE 2** | Fatigue generated titanium production by weight PROFEMUR® modular neck with increasing loads after 5.5 Million cycles



**FIGURE 3** | Fatigue generated titanium production by weight after 20 million cycles averaged to show weight loss per year

Another study<sup>13</sup> involved an accelerated cyclic loading test (10 Hz) in Ringer’s solution, comparing various implant body sizes to the weight loss. The implant tested has the same modular neck taper housing as the PROFEMUR® Hip. Increasing loading regimes were also used to evaluate weight loss. | **FIGURE 1** Testing was performed for 5.5 million cycles to approximate the first 5 years post-implantation. The testing on the larger stems was continued to 20 million cycles. Fretting wear was characterized by the post-test weight lost by the neck after separation from the neck taper housing and removal of the femoral head. | **FIGURE 2**

The weight loss due the head and neck taper could not be separated from the weight loss of the neck and body taper. The weight loss measurement was therefore entirely attributed to the neck and body taper. The larger stems exhibited the greater neck weight loss. It is noted that some weight loss comes from separating the neck/body taper, and the material lost probably would never spread out of the taper area. Estimated weight loss in the worst case modular neck junction (large stem) is 0.6 mg/year for the first 5 years and 0.1 mg/year for the next 15 years.

A normal and stable cementless hip implant “is likely to produce more than 10 mg/year of metal debris.” The amount of weight loss from the modular neck should therefore not have any significant effect. Dividing the 2.54mg total weight loss by 20 yields the amount of weight loss per 1 million cycles. Considering 1 million cycles to be equivalent to the number of cycles in 1 year allows direct comparison of weight loss per year to the 10mg weight loss from a cementless titanium stem cited in this reference. | **FIGURE 3**

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