

Taperloc Complete Hip System

Design Rationale



Taperloc Complete Hip System



Introduction

Over the past 26 years, the Taperloc Hip System has become the industry standard in cementless hip arthroplasty.¹ Combining unmatched clinical success with Zimmer Biomet's commitment to product innovation, the Taperloc Complete hip stem has been introduced with design enhancements that include a 133 degree neck angle, extended anterior-posterior neck flats, a smoothed distal transition and a polished neck. These enhancements, along with the key clinical aspects of the original Taperloc hip stem, are designed to help surgeons restore leg length, stability, offset and range of motion accurately and consistently.

Unmatched Clinical Results

In general, tapered titanium porous plasma-sprayed components have performed well in primary total hip arthroplasty (THA).² The Taperloc hip stem, in particular, is the longest clinically referenced primary hip stem with a wedge shape, titanium substrate and proximally circumferential titanium porous plasma sprayed design.³⁻⁵ Numerous short-term⁶, mid-term^{5,7,8} and long-term^{1,3,9-11} studies have demonstrated excellent clinical success of the Taperloc stem (Figure 1).

Author	Title	Publication/Date	Summary
McLaughlin, J.R. and Lee, K.R.	Survivorship 22 to 26 Years Reported with Uncemented Tapered Total Hip System	Orthopedics Today 30(1): 1, 2010	<ul style="list-style-type: none"> • 99% survivorship with revision for aseptic loosening as the end point • 145 hips • 138 patients • 22–26 follow-up (average 24.5 years)
McLaughlin, J.R. and Lee, K.R.	Cementless Total Hip Replacement Using Second-Generation Components: A 12 to 16 Year Follow up	The Journal of Bone and Joint Surgery (British) Vol. 92-B, No. 12, December 2010	<ul style="list-style-type: none"> • 99% survivorship with revision for any reason as the end-point • 123 Taperloc Reduced Distal stems implanted in 115 patients • 12 to 16 year follow-up (14 year mean) • No revisions for aseptic loosening • All femoral components achieved bone fixation • 1 femoral revision after a peri-prosthetic fracture of the femur one year after implantation
Keisu, K.S. et al.	Cementless Femoral Fixation in the Rheumatoid Patient Undergoing Total Hip Arthroplasty. Minimum 5 Year Results.	Journal of Arthroplasty 16(4): 415–21, 2001	<ul style="list-style-type: none"> • 100% survivorship • 49 Patients • 99% bony fixation • No intraoperative femoral fractures with insertion
Keisu, K.S. et al.	Primary Cementless Total Hip Arthroplasty in Octogenarians: Two to Eleven Year Follow-up	Journal of Bone and Joint Surgery 83: 359, 2001	<ul style="list-style-type: none"> • 100% survivorship • 114 Patients • No evidence of mechanical failure • All femoral implants had positive bone fixation
McLaughlin, J.R. and Lee, K.R.	Total Hip Arthroplasty in Young Patients. 8 to 13 Year Results Using an Uncemented Stem	Clinical Orthopaedics and Related Research 373: 135–62, 2000	<ul style="list-style-type: none"> • 98% survivorship • Low incidence of osteolysis (7%) • No revisions for aseptic loosening
Hozack, W.	Ten Year Experience with a Wedge Fit Stem	Crucial Decisions in Total Joint Replacement and Sports Medicine, 1998	<ul style="list-style-type: none"> • 99.6% survivorship • 4,750 patients • 12 year follow-up • 7 revisions for pain and loosening • 2 infections • 1 stem fracture
Hozack, WJ. et al.	Primary Cementless Hip Arthroplasty with a Titanium Plasma Sprayed Prosthesis	Clinical Orthopaedics and Related Research 333: 217–25, 1996	<ul style="list-style-type: none"> • No distal osteolysis • 102 Patients • No revision for aseptic loosening • Low incidence of thigh pain (4%)

Figure 1

Initial Taperloc Stem Design Rationale

The long-term clinical success of the Taperloc hip stem can be attributed to Zimmer Biomet's hip stem philosophy which has historically been based on four key characteristics for implant design:

- 3-degree bi-planar taper enhances proximal offloading, bone preservation and rotational stability^{5,12}
- Standard and high offset options accommodate various patient anatomies without lengthening the leg²
- Proximal, circumferential PPS (porous plasma spray) coating allows for initial scratch-fit stability and biologic fixation^{2,6,13,14}
- The flexibility of titanium alloy (Ti-6AL-4V) allows for stress transfer to preserve cortical density^{12,15}

3-degree Bi-planar Taper

The Taperloc stem was designed after the European philosophy of a flat tapered wedge. The collarless design provides for self-seating of the implant between the lateral and medial cortices of the femoral canal. The tapered portion of the stem provides a wedge effect in the medullary canal producing a medial/lateral wedge "fit" instead of a proximal "fit and fill" (Figure 2). Additionally, the wedge shaped design used in the typical ovoid femoral canal provides better rotational stability than femoral designs based on a round, intramedullary rod (Figure 3).¹⁶ This design provides rotational and axial loading with a proven lower incidence of thigh pain.¹¹⁻¹⁹

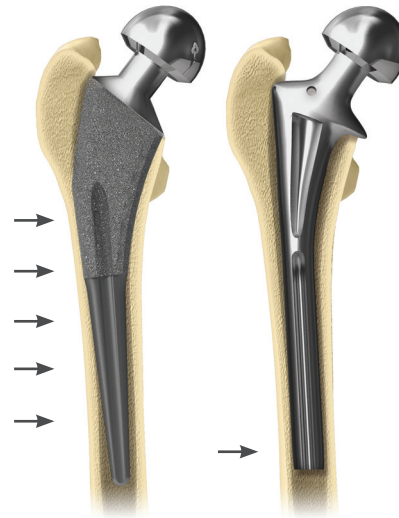


Figure 2

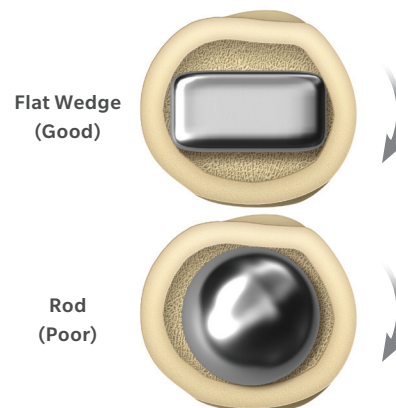


Figure 3: Femoral Component Rotational Fixation

Standard and High Offset Options

Achieving soft tissue tension is important for the success of THA. A femoral system with multiple offset options provide surgeons flexibility when matching the patient’s anatomy and increasing soft tissue tension (Figure 4). There are two design methods to achieve offset: a medial shift of the trunnion or a change in the neck angle (Figures 5 and 6).

The Taperloc stem design experiences lateralization through a constant, 7.8 mm medial shift of the trunnion. Shifting the neck geometry medially does not affect the neck height (thus, leg length) and allows the surgeon to change the stem from standard to high offset without having to reassess leg length.²⁰

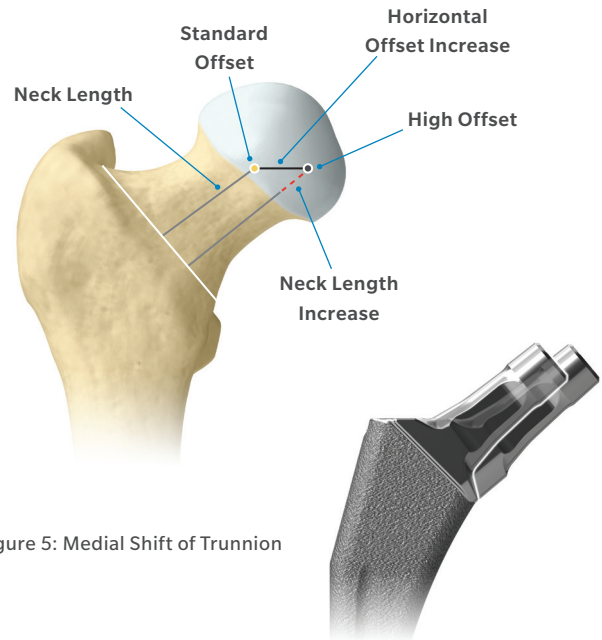


Figure 5: Medial Shift of Trunnion

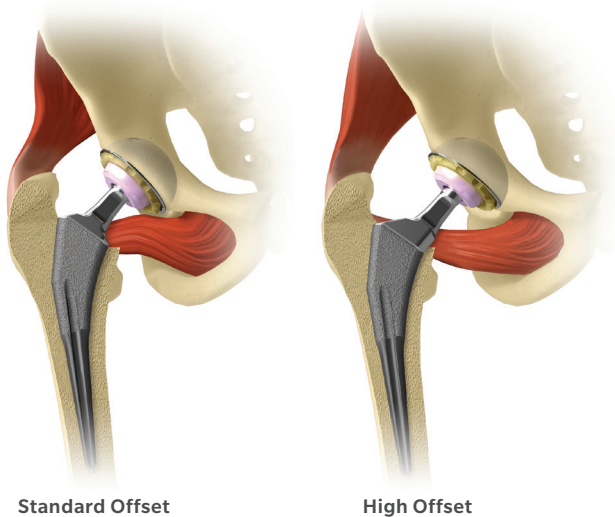


Figure 4

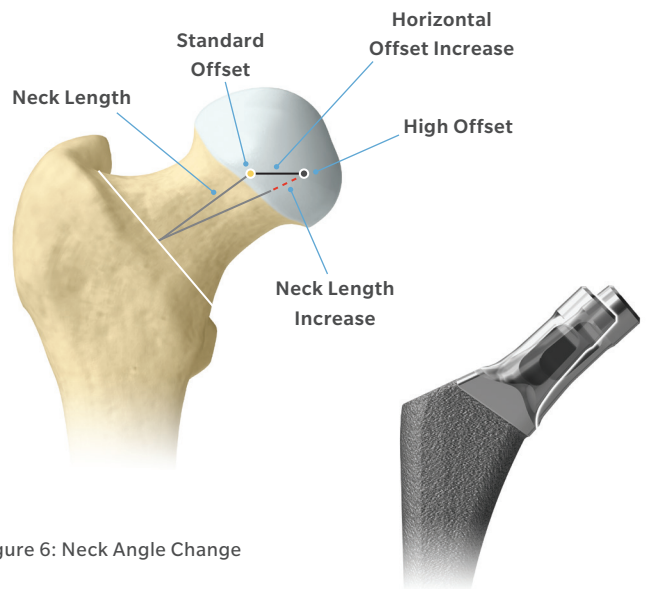


Figure 6: Neck Angle Change

Titanium Alloy (Ti-6AL-4V)

Zimmer Biomet was the first company to use titanium implants over 35 years ago and titanium has been proven to be extremely biocompatible. Its flexibility in hip stem applications allows for stress transfer to preserve cortical density.

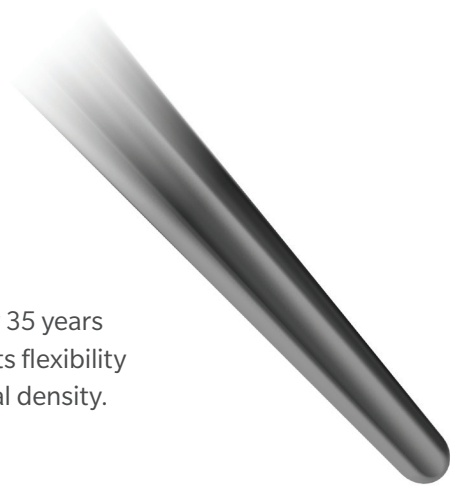


Figure 7

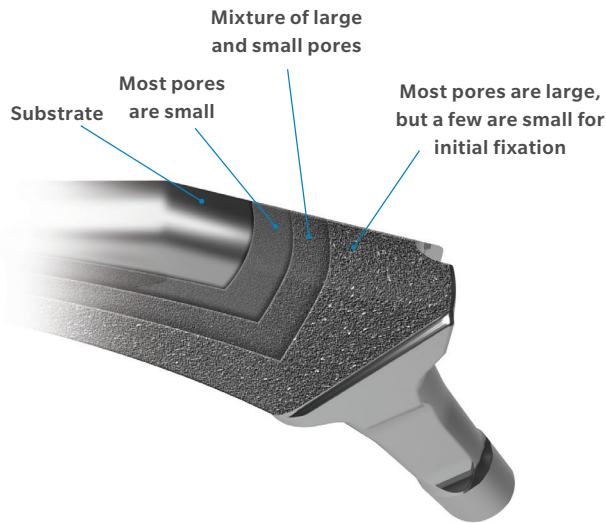


Figure 8

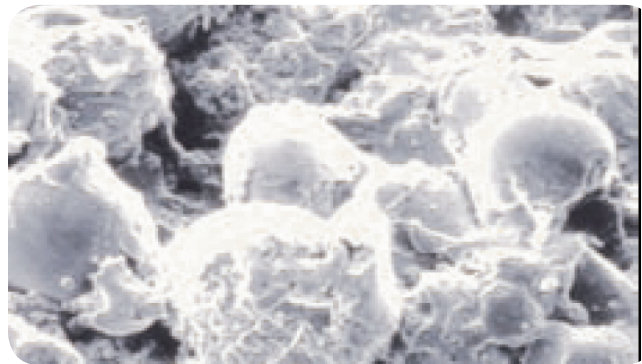


Figure 9: The irregularly shaped titanium particles sprayed onto the substrate result in a wide pore size distribution.

Circumferential PPS Coating

Zimmer Biomet was the first orthopedic company to introduce a plasma-sprayed prosthesis with the release of the PPS coated Taperloc hip stem in 1982. The Taperloc Complete stem features this same PPS coating, a proprietary process that is instrumental to Zimmer Biomet’s clinical success. The PPS application is unique in that only the titanium powder used to create the coating is heated, while the implant’s substrate is retained at near ambient temperatures. This unique process enables the implant to maintain its mechanical properties and has been shown to help guard against osteolysis and allow both immediate and long-term fixation.²¹⁻²³

The heating effect of the PPS process is transient (lasting only milliseconds). Therefore, the substrate material remains virtually unaffected and the fatigue properties are maintained.

Zimmer Biomet’s PPS coating has irregularly shaped molted titanium particles that splatter upon impactation with the substrate surface (Figures 8 and 9), creating a micro-rough texture and generating a wide distribution of pore size between 100 and 1,000 microns. The larger distribution of pore size, in conjunction with micro-rough texture and enhanced biocompatibility of titanium, allow for immediate fixation via mechanical interlocking and long-term biologic fixation. This has enabled Zimmer Biomet PPS coating’s clinically proven success for over 20 years, which has been documented in a variety of published clinical papers.^{21,22,24,25}

BoneMaster Nano-Crystalline HA Coating Technology

BoneMaster is an advanced biomimetic coating technology with the biological benefits of hydroxyapatite and an enhanced needle-like nano-structure based on apatite crystals found in bone (Figure 10).²⁶ This technology offers enhanced implant stability,²⁷ reduced fibrous in-growth^{2,3} and increased bone density.^{28,29}

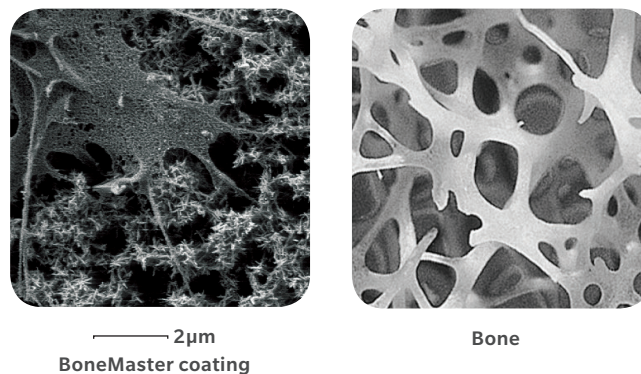


Figure 10

Enhances Implant Stability

Studies have demonstrated⁴ that the unique needle-like structure of BoneMaster significantly increases bone apposition compared to uncoated implants.

The unique needle-like topography of BoneMaster creates a favorable environment for osteoblast adhesion, producing faster bone integration. The BoneMaster coating is 1/10th of the thickness of plasma sprayed HA coating and therefore maintains the topography of the substrate. The 5µm thick BoneMaster coating preserves the macro-roughness and porosity of PPS (Porous Plasma Spray) Ti-alloy coating for enhanced primary and long-term fixation.³⁰⁻³²

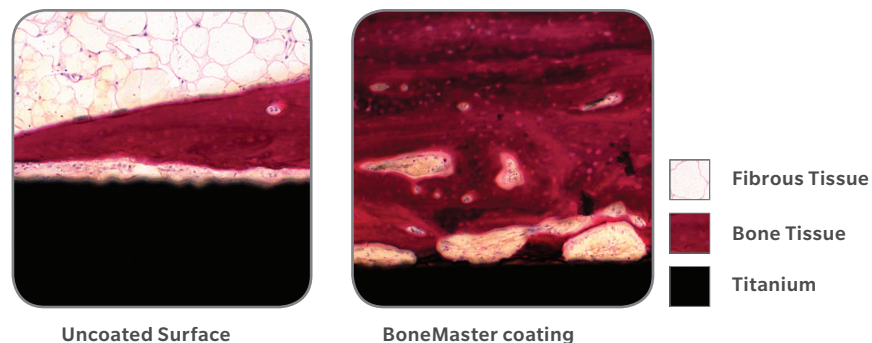


Figure 11

Reduces Fibrous on-growth

The unique needle-like nano-structure of BoneMaster results in its excellent osteoconductivity, as a result of the close resemblance to the apatite found in bone. The nanocrystalline hydroxyapatite structure of BoneMaster promotes faster bone in-growth and bone apposition resulting in reduced fibrous in-growth^{27,28} (Figure 12).

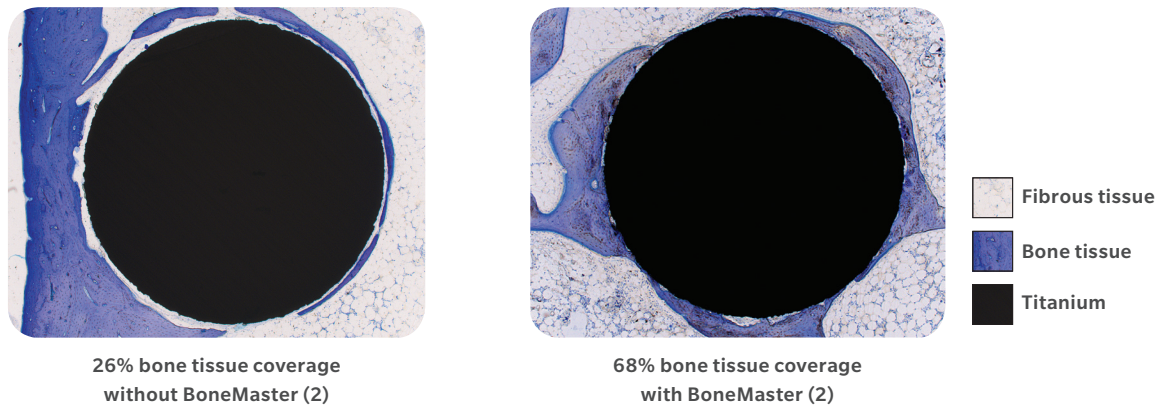


Figure 12: Bone/Implant interface

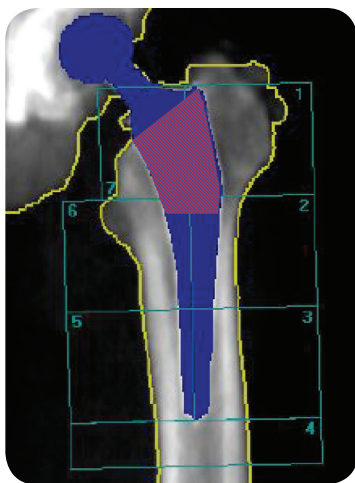


Figure 13

Increased Bone Density

In a clinical study,³³ BoneMaster coated stems showed significantly greater bone density post-operatively, compared to identical plasma-sprayed HA stems. Professor Lars Nordsletten, PhD, MD, has reported results at 12 and 24 months post-operatively, showing a greater bone density surrounding the BoneMaster coated stems compared with the plasma HA coated stems; especially in the coated area: Gruen zone 1, where there was a significant increase in bone density compared to conventional HA coating (Figure 13).

Taperloc Complete Design Features

The Taperloc Complete stem design is based upon the same key design principles of the Taperloc stem released in 1982, but incorporates additional features such as a 133 degree neck angle, polished extended anterior-posterior neck flats, a smooth distal transition and a modified insertion hole. These enhancements are designed to improve range of motion (ROM) as well as increase neck fatigue resistance to better address surgeon and patient needs.^{20,34}

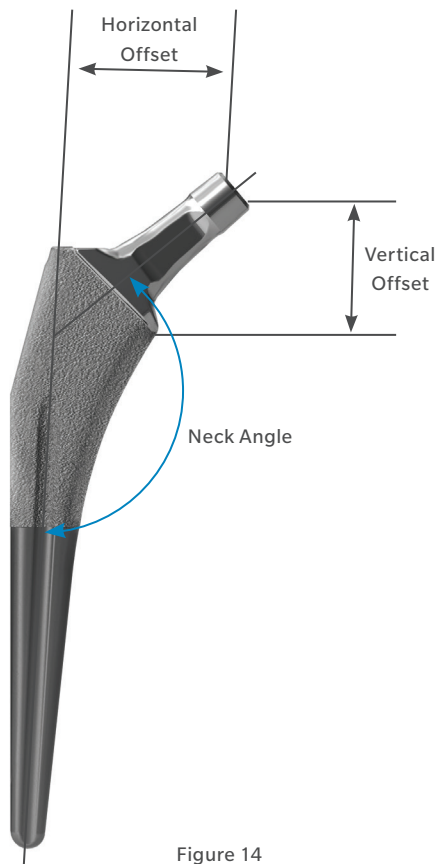


Figure 14

133 degree Neck Angle

There are many facets of stem design that influence ROM, including the shape and diameter of the neck, neck/head ratio, the position of the rotation center relative to the opening plane of the cup, and the specific design of the opening plane itself.³⁴ One of the most important design considerations of a femoral stem is the horizontal offset, defined as the perpendicular distance from the center of rotation of the femoral head to a line bisecting the long axis of the femur (Figure 14).

Increasing the horizontal offset, which moves the femur laterally, will decrease impingement, increase ROM, and improve soft tissue tension resulting in better stability without lengthening the leg.^{20,34} In general, a low neck angle allows for a larger horizontal offset to be achieved with less effect on leg length.

The charts below compare the offsets of the Taperloc and Taperloc Complete stem designs for 5, 10 and 20 mm stem sizes. The Taperloc Complete stem has an increased horizontal offset and reduced vertical offset which biomechanically provides enhanced stability. In addition to obtaining improved stability, the change to offsets allow for more use of the standard and +3 modular head options. This allows for a better reproduction of hip biomechanics and enhanced intraoperative flexibility allowing the surgeon to utilize additional modular head options if needed.

Size	Taperloc Stem- Standard Offset		Taperloc Complete Stem - Standard Offset		Taperloc Complete Stem - XR 123°	
	Horizontal Offset	Vertical Offset	Horizontal Offset	Vertical Offset	Horizontal Offset	Vertical Offset
5	34	35	36.1	32.9	38.8	26.9
10	36.5	35	38.6	32.9	40.8	26.9

15	41.5	35	45.8	34.9	—	—
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Size	Taperloc Stem - High Offset		Taperloc Complete Stem - High Offset		Taperloc Complete Stem - XR 123°	
	Horizontal Offset	Vertical Offset	Horizontal Offset	Vertical Offset	Horizontal Offset	Vertical Offset
5	41.8	35.6	43.9	32.9	38.8	26.9
10	44.3	35.6	46.4	32.9	40.8	26.9
15	49.3	35.6	53.6	34.9	—	—

Another advantage of lowering the neck angle is to increase the “safe-zone” for compliant cup orientations. A safe-zone is the maximum allowable ROM before the femoral neck impinges on the acetabular component (Figure 15). Neck angles above 135 degrees have a reduced safe-zone range and may not allow for the ideal/maximum ROM.³⁴

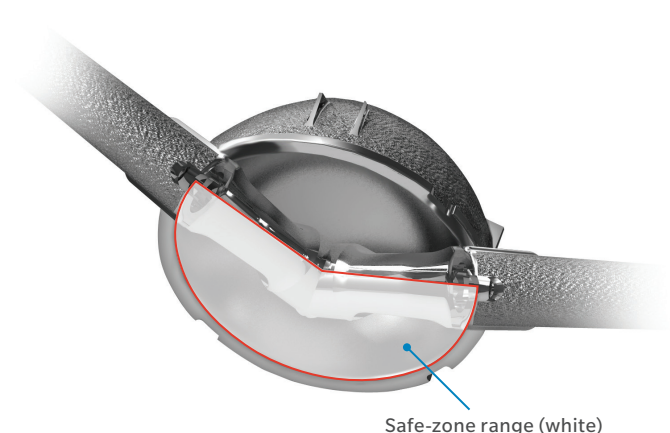


Figure 15

* Femoral head removed for clarity

In addition to increasing the safe-zone range, the 133 degree neck angle of the Taperloc Complete stem and the 123 degree neck angle of the Taperloc Complete XR 123° stem provide an increase in total flexion and extension compared to femoral designs with neck geometry greater than 135 degrees (Figures 16 and 17).

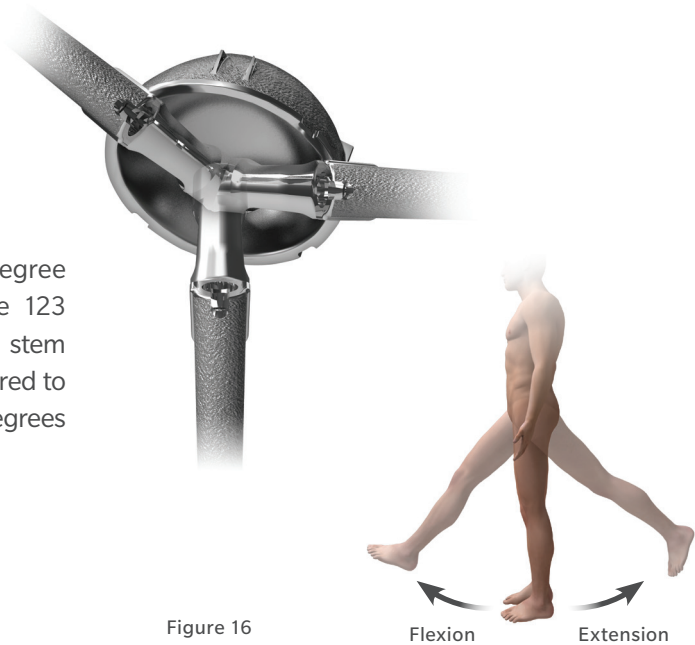


Figure 16
* Femoral head removed for clarity

Description		Flexion	Extension	Total
Stem	10 mm Taperloc Complete Stem (123° neck angle)			
Acetabular Options	54 mm shell			
Head Size	48 mm head	158°	116°	274°
Taper Inserts	Standard			
Stem	10 mm Taperloc Complete Stem (133° neck angle)			
Acetabular Option	54 mm shell			
Head Size	48 mm head	136°	93°	229°
Taper Insert	Standard			
Stem	10 mm Taperloc Complete Stem (138° neck angle)			
Acetabular Option	54 mm shell			
Head Size	48 mm head	131°	90°	221°
Taper Insert	Standard			

Figure 17: The chart above illustrates the increased flexion and extension that is achieved with the 133 and 123 degree neck angle of the Taperloc Complete stems in comparison to the 138 degree neck angle of the 1982 Taperloc stem design. This study was conducted using an acetabular component (54 mm shell and 48 mm head) with a cup placement of 45 degree abduction, 15 degree anteversion and a stem placement of 10 degree adduction.³⁵

Polished Anterior-Posterior Neck Flats

Opposing anterior-posterior flats along the neck below the taper, increase ROM by geometrically reducing the potential for impingement of the neck with the cup.³⁴ The highly polished neck increases the material strength providing additional neck fatigue resistance.³⁶

Implant sizing

The Taperloc Complete stem is offered in 1 mm increment sizing for optimal interchangeability, O.R. efficiency and accurate matching of the patient’s femur without the need to remove additional bone. There are 18 total sizes ranging from size 4–18 mm in 1 mm increments. The size of the implant is measured 100 mm distal from the medial resection level. The stem grows incrementally with each stem size. The medial curvature remains constant for each size and grows outward laterally (Figure 18).

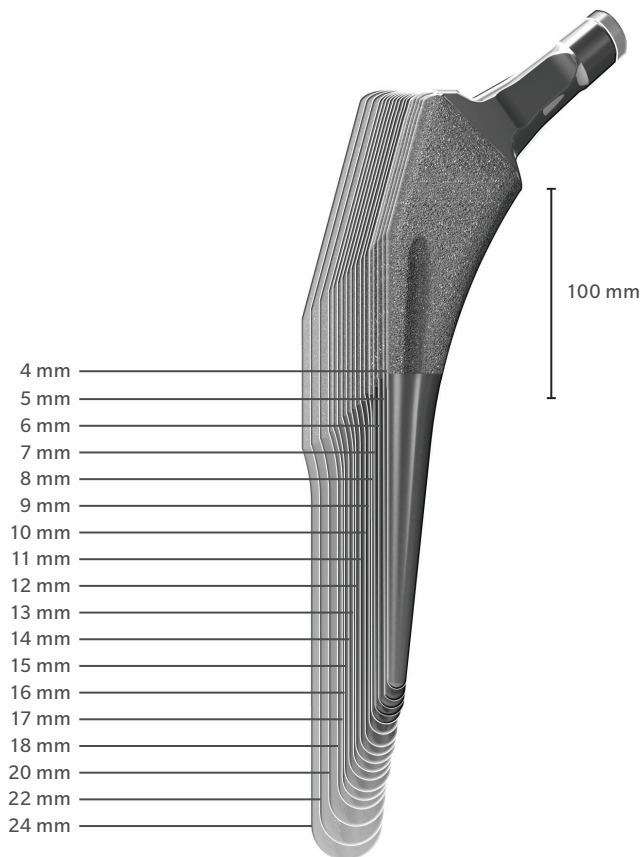


Figure 18

* Femoral head removed for clarity

Full Profile Option

The full length, full profile Taperloc Complete stem option has the same metaphyseal and diaphyseal geometry as the Taperloc stem released in 1982, but incorporates the modified neck of the Taperloc Complete System. This stem geometry is based upon the original Taperloc design that has been clinically proven for over 26 years in a variety of patient types.¹

Reduced Distal Option

The Taperloc Complete stem features a reduced distal geometry in which a gradual reduction of the stem substrate occurs distal to the porous coating level. The Taperloc Complete stem’s reduced distal geometry enhances the proximal fill of the implant in the metaphysis. This particular design is the optimal choice to address a proximal/distal mismatch, which is common in a Dorr Type A femur, by properly accommodating the proximal metaphysis without the need to fit a narrow distal femoral geometry (Figure 19). This design enhancement is based on the traditional Taperloc Reduced Distal stem which has been clinically successful for over 16 years.³⁷



Figure 19: The Taperloc Complete stem accommodates the proximal metaphysis without the need to fit a narrow distal femoral geometry

The profile of the Taperloc Complete stem is unique in that the reduction of the distal portion of the stem begins at size 9 mm and progressively increases as the stem size increases (Figure 16). For example, the size 15 mm standard profile Taperloc stem (component A) measures 15 mm in diameter, 100 mm distal from the medial resection level. A 15 mm reduced distal Taperloc Complete stem (component B) measures 12 mm in diameter, 100 mm distal from the medial resection level (Figure 20).

Stem Size	Distal Reduction
9 mm	1 mm
10 - 13 mm	2 mm
14 - 16 mm	3 mm
17 - 24 mm	4 mm

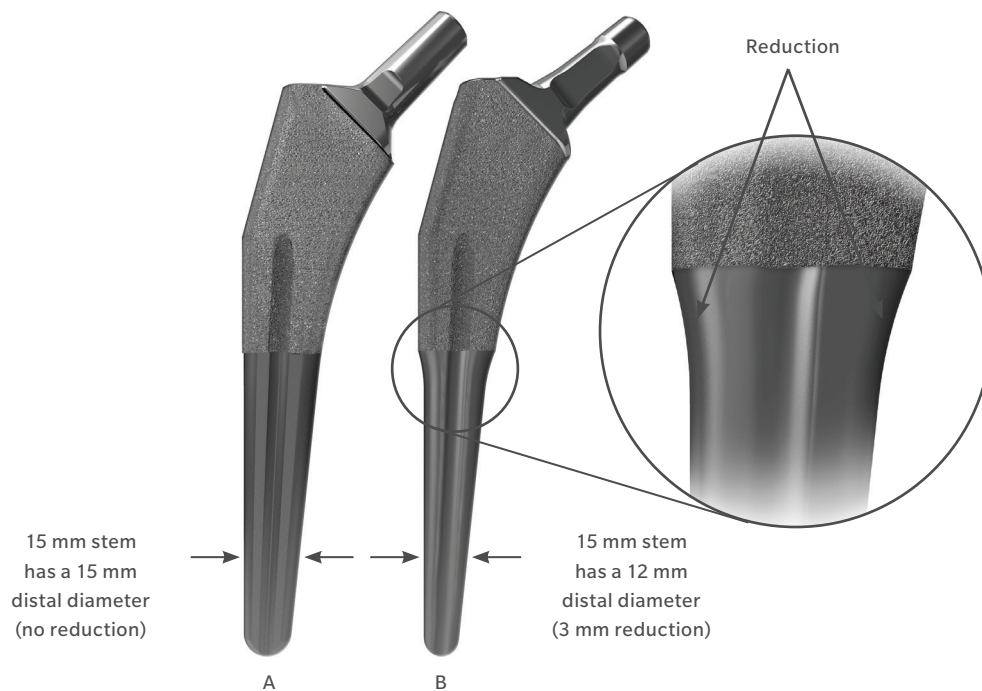


Figure 20

Taperloc Complete Microplasty® Stem

The Taperloc Complete Microplasty stem was originally designed for ease of insertion when utilizing an Anterior Supine Intramuscular (ASI) approach. The stem length is reduced by 35 mm from the Taperloc Complete standard stem, yet maintains the same proximal geometry (Figure 21). The shorter length provides a bone conserving stem option to facilitate minimally invasive techniques, provides an alternative to femoral resurfacing and offers a unique solution in cases where a bone conserving prosthesis is desirable (Figure 22).

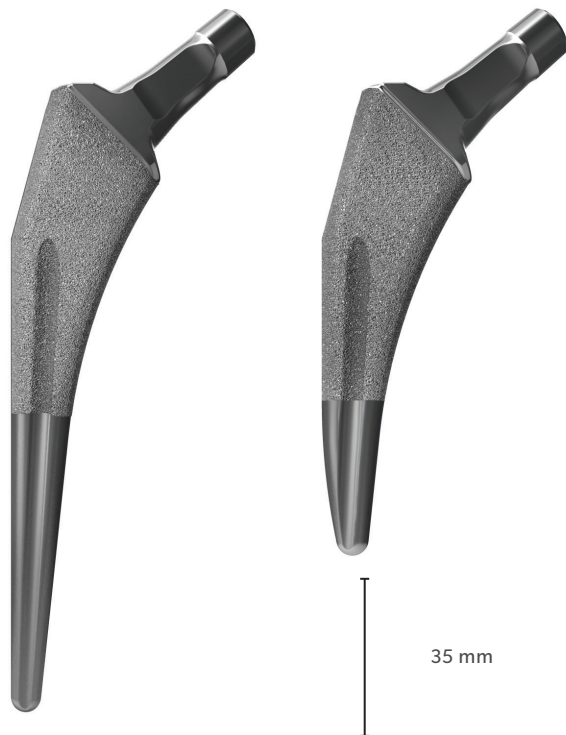


Figure 21: The Taperloc Microplasty stem length is reduced by 35 mm from the standard length stem.

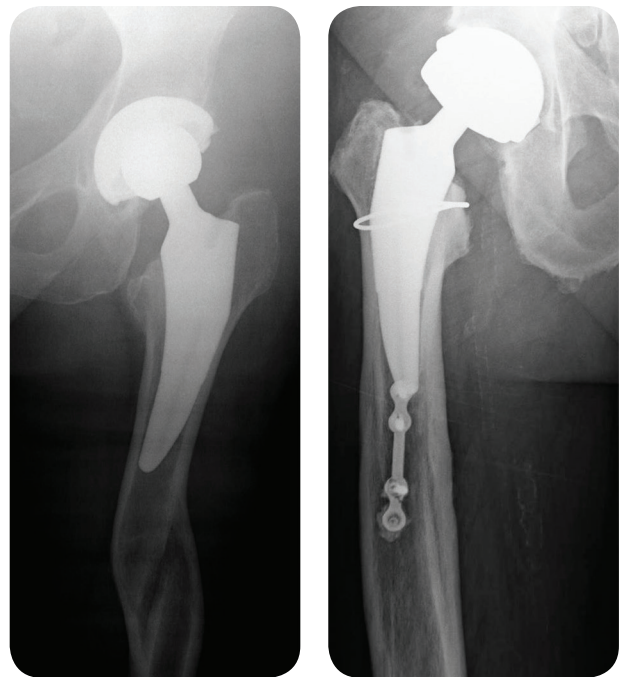


Figure 22



Figure 23: The Taperloc Complete Microplasty stem has the same design enhancements as the full length Taperloc Complete stem, including a reduced distal geometry. For sizes 9 mm and larger, the Taperloc Complete Microplasty stem has a smooth distal reduction to better maximize metaphyseal fit.

Taperloc Complete Microplasty XR 123° Stem

The Taperloc Complete XR 123° stem option has the same stem geometry as the Taperloc Complete Microplasty stem, but features a 123 degree neck angle and a neck length that is 2 mm shorter. These unique design features help to address femurs with a more varus neck by allowing for additional horizontal offset and lower vertical offset to properly restore hip biomechanics and soft tissue tensioning.

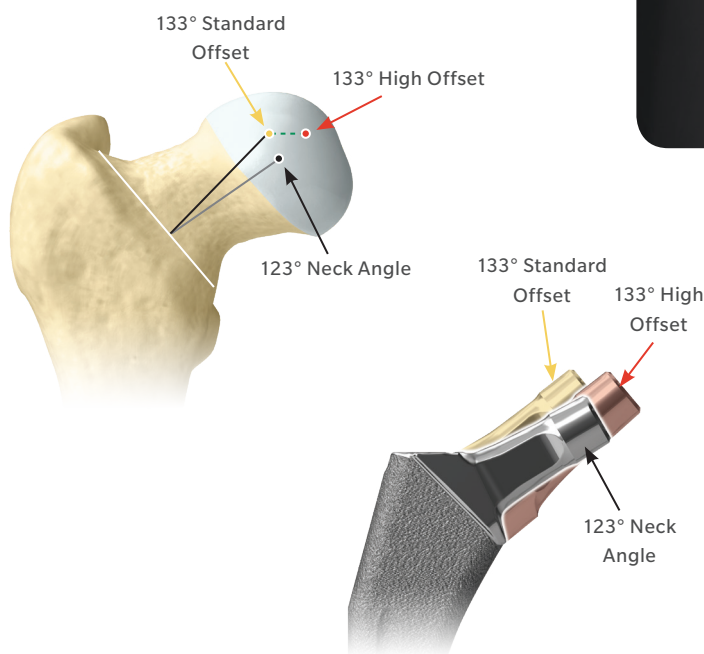


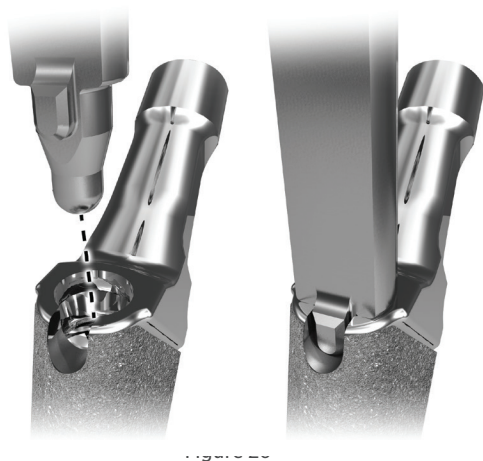
Figure 24: The bone illustration above represents varus anatomy

Offset Option	Size	Neck Angle	Neck Length (mm)	Horizontal Offset (mm)	Vertical Offset (mm)
Standard	9 mm	133°	34.3	38.1	32.9
High Offset	9 mm	133°	39.6	45.9	32.9
XR 123	9 mm	123°	32.3	40.3	26.9

Figure 25: The chart above compares the neck angle, neck length and offset achieved with the various options available in the Taperloc Complete System

Rational Stability Insertion Hole

The modified insertion hole offers built-in rotational control providing additional stability upon stem insertion without the need to engage the neck (Figure 26). This design concept is similar to that of the Taperloc broach/broach handle, giving the surgeon a more secure feel during stem insertion.



Instrumentation

The Taperloc Complete stem utilizes a simple, reproducible broach only surgical technique. The philosophy of a tapered wedge style stem lends itself to the use of a minimal amount of instrumentation resulting in an easy, efficient surgical technique that has proven to be clinically successful. The Taperloc Complete broach instrumentation is designed to incorporate a tight press-fit upon implantation of the final femoral component relative to the broach.

The Taperloc Complete broach will rasp away bone to match the titanium substrate of the implant and not the PPS coating, in the anterior-posterior region of the stem. However, medial-laterally the broach will rasp bone to match the size of the implant including the PPS coating. Thus, when the surgeon chooses their final implant it will achieve a 1–1.5 mm PPS press-fit in the anterior posterior regions (Figure 27). Distal to the PPS coated region, the broach and implant substrate are line-to-line in both medial-lateral and anterior-posterior regions.

Additionally, there are a variety of other Zimmer Biomet femoral preparation instruments including straight, curved, and offset stem inserters, broach handles, and various femoral preparation instruments to best meet surgeons' needs.

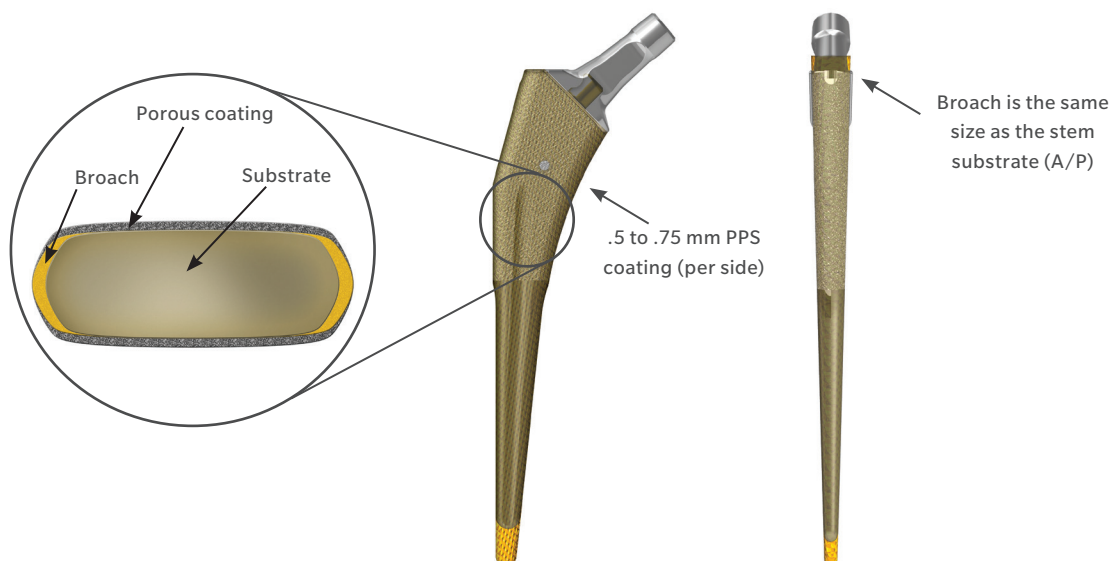


Figure 27

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