Taperloc® Complete Hip Stem

Design Rationale
Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it’s meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally-invasive surgical technique, advanced biomaterials, or a custom, patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.
Introduction

Over the past 26 years, the Taperloc® Hip System has become the industry standard in cementless hip arthroplasty. Combining unmatched clinical success with 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). 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. Numerous short-term, mid-term, and long-term studies have demonstrated excellent clinical success of the Taperloc® stem (Figure 1).

<table>
<thead>
<tr>
<th>Author</th>
<th>Title</th>
<th>Publication/Date</th>
<th>Summary</th>
</tr>
</thead>
</table>
| 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 | • 98% survivorship  
• Low incidence of osteolysis (7%)  
• No revisions for aseptic loosening |
| 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     | • 100% survivorship  
• No evidence of mechanical failure  
• All femoral implants had positive bone fixation |
• 99% bony fixation  
• No intraoperative femoral fractures with insertion |
| Hozack, W.          | Ten Year Experience with a Wedge Fit Stem                             | Crucial Decisions in Total Joint Replacement and Sports Medicine, 1998 | • 99.6% survivorship  
• 4,750 patients  
• 12 year follow-up  
• 7 revisions for pain and loosening  
• 2 infections  
• 1 stem fracture |
| McLaughlin, J.R. and Lee, K.R. | Survivorship at 22 to 26 Years Reported with Uncemented Tapered Total Hip Stem | Orthopedics Today 30(1): 1, 2010                   | • 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 | • 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 |
• 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 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 leg\(^2\)
- Proximal, circumferential PPS\(^\circledR\) (porous plasma spray) coating allows for initial scratch-fit stability and bony 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\(^\circledR\) 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.\(^11-19\)
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.26

Figure 4

Figure 5: Medial Shift of Trunnion

Figure 6: Neck Angle Change
Circumferential PPS® Coating

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 Biomet’s clinical success. The PPS® plasma spray 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.5,7,20–22

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.

Biomet’s PPS® coating has irregularly shaped molten titanium particles that splatter upon impaction with the substrate surface (Figures 7 and 8), 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 Biomet PPS® coating’s clinically proven success for over 20 years, which has been documented in a variety of published clinical papers.5,7,17,20,21,23,24

Titanium Alloy (Ti-6AL-4V)

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

Figure 7

Figure 9
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 ROM as well as increase neck fatigue resistance to better address surgeon and patient needs.\textsuperscript{25,26}

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.\textsuperscript{25} 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 10).

Increasing the horizontal offset, which moves the femur laterally, will decrease impingement, increase range of motion (ROM), and improve soft tissue tension resulting in better stability without lengthening the leg.\textsuperscript{25,26} 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.

<table>
<thead>
<tr>
<th>Taperloc® Stem – Standard Offset</th>
<th>Taperloc® Complete Stem – Standard Offset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>Horizontal Offset</td>
</tr>
<tr>
<td>5</td>
<td>34</td>
</tr>
<tr>
<td>10</td>
<td>36.5</td>
</tr>
<tr>
<td>20</td>
<td>41.5</td>
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<table>
<thead>
<tr>
<th>Taperloc® Stem – High Offset</th>
<th>Taperloc® Complete Stem – High Offset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>Horizontal Offset</td>
</tr>
<tr>
<td>5</td>
<td>41.8</td>
</tr>
<tr>
<td>10</td>
<td>44.3</td>
</tr>
<tr>
<td>20</td>
<td>49.3</td>
</tr>
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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 11). Neck angles above 135 degrees have a reduced safe-zone range and do not allow for the ideal/maximum ROM.25

Figure 11: Note: Femoral head removed for clarity.
In addition to increasing the safe-zone range, the 133 degree neck angle of the Taperloc® Complete stem provides for an increase in total flexion and extension compared to femoral designs with neck geometry greater than 135 degrees (Figures 12 and 13).

![Figure 12: Note: Femoral head removed for clarity.](image)

<table>
<thead>
<tr>
<th>Description</th>
<th>Flexion</th>
<th>Extension</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stem:</strong> 10 mm Taperloc® Complete stem (133° neck angle) standard offset</td>
<td>128°</td>
<td>87°</td>
<td>216°</td>
</tr>
<tr>
<td><strong>Acetabular Option:</strong> 54 mm M²a-Magnum™ shell</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Head Size:</strong> 48 mm M²a-Magnum™ head</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Taper Insert:</strong> Standard</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stem:</strong> 10 mm Taperloc® stem (138° neck angle) standard offset</td>
<td>124°</td>
<td>83°</td>
<td>208°</td>
</tr>
<tr>
<td><strong>Acetabular Option:</strong> 54 mm M²a-Magnum™ shell</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Head Size:</strong> 48 mm M²a-Magnum™ head</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Taper Insert:</strong> Standard</td>
<td></td>
<td></td>
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</table>

*Figure 12: The chart above illustrates the increased flexion and extension that is achieved with the 133 degree neck angle of the Taperloc® Complete stem in comparison to the 138 degree neck angle of the 1982 Taperloc® stem design. This study was conducted using an M²a-Magnum™ acetabular component with a cup placement of 45 degrees abduction, 15 degrees anteverision and a stem placement of 10 degrees adduction.*

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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. The highly polished neck increases the material strength providing additional neck fatigue resistance.

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 17 total sizes ranging from size 5–18 mm in 1 mm increments in addition to size 20, 22 and 24. 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 14).

Smooth Distal Transition
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 15). This design enhancement is based on the traditional Taperloc® Reduced Distal stem which has been clinically successfully for over 16 years.

Figure 14: 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 17).

<table>
<thead>
<tr>
<th>Stem Size</th>
<th>Distal reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 mm</td>
<td>1 mm</td>
</tr>
<tr>
<td>10–13 mm</td>
<td>2 mm</td>
</tr>
<tr>
<td>14–16 mm</td>
<td>3 mm</td>
</tr>
<tr>
<td>17–24 mm</td>
<td>4 mm</td>
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Rotational 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 18). 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 19). 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 Biomet® femoral preparation instruments including straight, curved, and offset stem inserters, broach handles, and various femoral preparation instruments to best meet surgeons’ needs.
References


