# EXACTECH | HIP

## Design Rationale

# ALTEON®

**Tapered Wedge Femoral Stem**

Exactech®

*Surgeon focused. Patient driven.™*

ALTEON®

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The word "Alteon" is derived from the Latin word "altus" meaning "high," denoting Exactech's high performance, next-generation hip system. This system is designed to deliver a reproducible, efficient and predictable clinical experience.

# Introduction

The Alteon® Tapered Wedge is a next-generation, single-taper, wedge-style stem. It incorporates specific philosophies, and is designed to improve surgical experiences and clinical outcomes.

The Tapered Wedge collarless design intends to achieve immediate axial and rotational mechanical stability between the medial and lateral cortices of the femoral canal. This is achieved through a proprietary combination of:

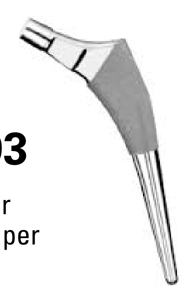
- Optimized proximal/distal geometry
- Six degree single medial/lateral (M/L) taper
- Interconnected macro-pore titanium plasma coating
- Incremental sizing
- Lateral flare geometry
- Distal corner radii
- Varus relief

## FIRST GENERATION

**1981**
DePuy Tri-Lock

**1982**
Biomet TaperLoc

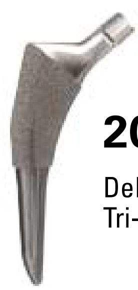
**2001**
Stryker
Accolade



**2003**
Zimmer
M/L Taper

## SECOND GENERATION

**2008**
Biomet
TaperLoc
Complete
(RDD)



**2009**
DePuy
Tri-Lock BPS

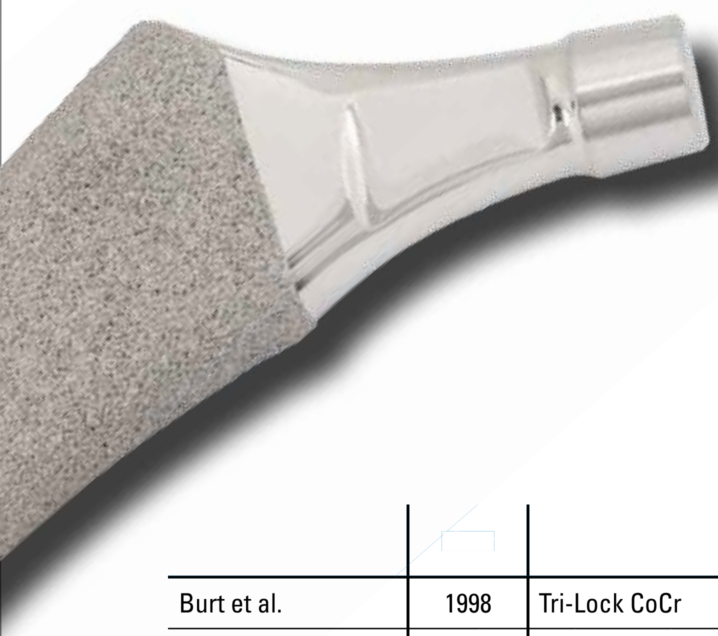
**2012**
Stryker
Accolade II

## NEXT GENERATION

# Design History and Evolution of Wedge Stems

Previous iterations of single-taper, wedge-style stems can generally be classified into first- and second-generation designs. Traditional, first-generation, single-taper wedge stems are based off the cemented Mueller stem of the 1970s. These stems initially featured proximally coated, cobalt chrome implants that quickly evolved to titanium alloy. These first-generation implants were typically longer in overall size and featured a more robust distal shape.

Single-taper, wedge-style stems showed continued evolution over the last thirty years. As the industry continued to advance in the area of materials, and changes to the stem and head prostheses emerged, the transition from first- to second-generation stems occurred. This eventually led to design modifications that included, but are not limited to: cut off or shorter overall prosthesis length, reduced distal geometry stems, and modular necks to account for varying anatomical morphologies. Most of these designs also featured a constant medial curvature throughout the entire size range and grew laterally with size, the exception being the Accolade II design.



## Summary of Success

Healy et al. noted that a “flat, tapered wedge femoral stem design provides excellent femoral reconstruction for total hip arthroplasty (THA).”[1] The table below highlights the implant survivorship of both first- and second-generation, single-taper wedge stem designs.[1-9]

| | | | ype Name | # of Hips | Aseptic Survivorship of Stem |
|---|---|---|---|---|---|
| Burt et al. | 1998 | Tri-Lock CoCr | First Generation | 44 | 98.0% @ 10 years |
| Parvizi et al. | 2004 | Taperloc | First Generation | 111 | 99.1% @ 10 years |
| Lettich et al. | 2007 | Accolade I | First Generation | 547 | 99.4% @ 4.35 years |
| McLaughlin et al. | 2008 | Taperloc | First Generation | 145 | 99.0% @ 22 years |
| Healy et al. | 2009 | Tri-Lock CoCr<br>Tri-Lock Titanium | First Generation | 358 | 99.5% @ 4.7 years |
| White et al. | 2012 | Accolade I | First Generation | 367 | 97.0% @ 5 years |
| McLaughlin et al. | 2010 | Taperloc RDD | Second Generation | 123 | 99.0% @ 16 years |
| McLaughlin et al. | 2011 | Taperloc | First Generation | 76 | 97.0% @ 18 years |
| Costa et al. | 2012 | Accolade I | First Generation | 35 | 96.0% @ 4.5 years |

# Unmet Clinical Needs

Distal Potting of a Zimmer M/L Taper Stem in Type A Femora

## DISTAL POTTING OF THE FEMORAL STEM

In spite of historical implant success, several clinical challenges remained unaddressed with the second-generation implant designs. One of these challenges is proper medial/lateral fixation of the tapered wedge implant in femurs that have a substantially greater proximal/distal canal mismatch. Cooper et al. noted that risk factors associated with failure of osseointegration (of the implant) included a smaller canal-flare index, and a greater canal fill at the mid-and distal-thirds of the stem.[10] This complication, where an implant fills the femoral canal distally before M/L fixation is achieved proximally, is most often seen in Dorr Type A Femora and is commonly referred to as "distal potting" of the implant.

Delayed Implant Subsidence

## DELAYED IMPLANT OSSEOINTEGRATION & SUBSIDENCE

Another clinical issue presented with first-generation versus current single-taper, wedge-style stems was migration of the femoral stem. A retrospective analysis conducted by White et al. demonstrated a "high incidence of migration" of the Accolade I.[6]

The average subsidence of the Accolade I device at 24 months was 1.3mm with five-year survivorship for aseptic loosening to be 97 percent with revision as an endpoint and 95 percent for radiographic failure.[6] This study noted that factors predictive of migration included larger stem size, lower canal flare index (i.e. Dorr A Femora), and the implant having a lower modulus of elasticity (making it more flexible) compared to traditional titanium alloys.

Jacobs and Christensen reported that "many factors influence implant migration in the first postoperative year including, sex, age, weight and activity level; and design characteristics of the femoral stem." Their study also showed "significant progressive subsidence" between the six-week and annual follow-ups of patients who had first-generation, cementless wedge stems implanted.[11]

## PERIPROSTHETIC FRACTURES

Studies have reported that periprosthetic fractures following primary total hip arthroplasty performed using a non-cemented tapered wedge stem design have increased since their first introduction. Cooper and Rodriguez suggest the increased incidence of periprosthetic fractures in first-generation, single-taper wedge stem designs (Accolade I) may be due to "the hand broached preparation technique necessary to achieve a tight press-fit for immediate component stability, or due to the wedge-shaped design of this (particular) implant." The incidence of these fractures is relatively low (a range of 0.4 percent to 0.6 percent) but it is suggested that different implant taper geometries may allow one to avoid this problem.[10]


**Periprosthetic Fracture with Taperloc Microplasty Stem**

## THIGH PAIN

Healy conducted a prospective randomized study to evaluate the incidence of thigh pain in patients who received a non-cemented, first-generation wedge-style stem. The study showed 20/390 or 5.1 percent of the patient cohort presenting with thigh pain. The study also showed that the incidence of thigh pain was greater in patients who received the cobalt chromium implant versus those that received the titanium implant.[1] It has also been noted that second-generation wedge stems also present with thigh pain, consistent with the first-generation press-fit designs.

# Exactech Implant Design Philosophy for Tapered Wedge

Since its founding in 1985, Exactech has operated with a primary goal of providing implants and services that seek to improve patient outcomes. The Tapered Wedge Surgeon Design team, Jeff Pierson, MD, (Franciscan St. Francis Health, Carmel, Indiana) and Micahel Kang, MD, (Insall Scott Kelly Institute, New York , New York), alongside our engineering team, set out with several design goals in mind to address the clinical challenges previously mentioned.

## DESIGN GOALS

1) The proximal/distal stem ratio should allow the implant to achieve fixation in all primary femur types (Dorr A,B,C) without compromising implant features or surgical technique. Specifically, there is a need to be able to address Dorr A Femora where distal reaming may be required for competitive designs.

2) The stem should be able to solve common kinematic issues without the need for modular neck components.

3) The stem should never exceed 1.25mm in growth throughout the distal body in order to avoid jumps in size that may be too large.

4) The femoral stem shall achieve immediate axial and rotational stability.

5) The stem should incorporate features that allow compatibility with all surgical approaches, but not compromise the ability of the geometric features to provide mechanical fixation (i.e. length of the stem is not too short to provide the potential for three-point fixation).

**Alteon Tapered Wedge Femoral Stem**

## PROXIMAL/DISTAL GEOMETRY

The combination six degree single M/L taper and three degree anterior/posterior (A/P) taper of the femoral stem provides an intentional wedge-fit within the metaphysis of the proximal femoral canal that is in strong contrast to occasional diaphyseal fixation seen with first- and some second-generation wedge stems. It has been reported that distal fixation of first-generation single-taper wedge stems leads to higher than expected failure rates for osseointegration, migration and loosening.[6, 11]

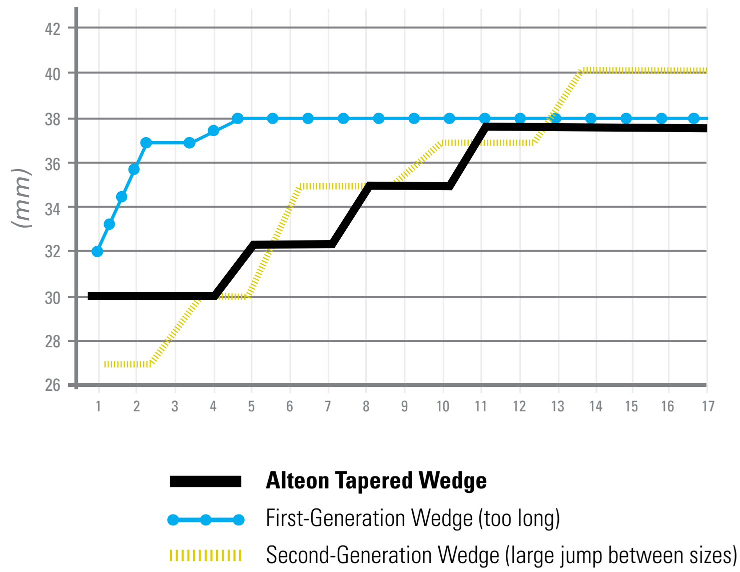
In order to achieve the first design goal, Alteon Tapered Wedge features an optimized overall length and proximal/distal sizing to achieve fixation in all primary femur types (Dorr A, B, C) without compromising implant features or surgical technique.[12] In addition, the Tapered Wedge maintains all levels of fixation available without compromising one by shortening the overall length of the stem. The design still incorporates a reduced distal geometric shape, as compared to other single-taper wedge stems available in the market.[12]

## INCREMENTAL SIZING

In order to satisfy design goal number two, solving common kinematic issues without the need for modular necks, careful consideration was taken when designing the neck grouping scheme for the Tapered Wedge stem. Some first- and second-generation competitive designs feature base neck lengths that are too large, have too large of a jump between stem sizes, or require modularity in order to solve kinematic issues during the surgical procedure.[12]

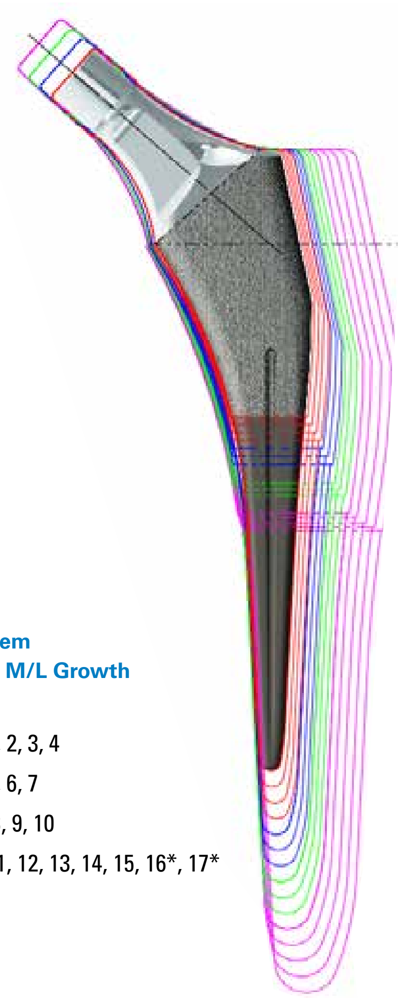
The Tapered Wedge stem has four base neck length groups. The system was intentionally designed so that a change between the neck length groupings could be accommodated by changing the modular femoral head offset, without affecting the overall total leg length. Additionally, the stem has two offsets, standard and extended, that share a 131-degree neck angle, enabling offset adjustments without affecting leg length.

**Standard Base Neck Length**




## Implant Growth

In order to satisfy the third design goal, the Alteon Tapered Wedge intentionally grows at a smaller rate lateral and distal (in the smaller stem sizes) when compared to the previous generation wedge stems. Consequentially, the Tapered Wedge system offers more sizes, versus some second-generation stems, to accommodate a comparable size femur.



**Alteon Tapered Wedge System**
**Neck Length Grouping and M/L Growth**

Group 1 = Sizes 1, 2, 3, 4
Group 2 = Sizes 5, 6, 7
Group 3 = Sizes, 8, 9, 10
Group 4 = Sizes 11, 12, 13, 14, 15, 16*, 17*

**Items are special order.*

In order to achieve immediate axial and rotational stability of the implant, several geometric features were designed into the implant.

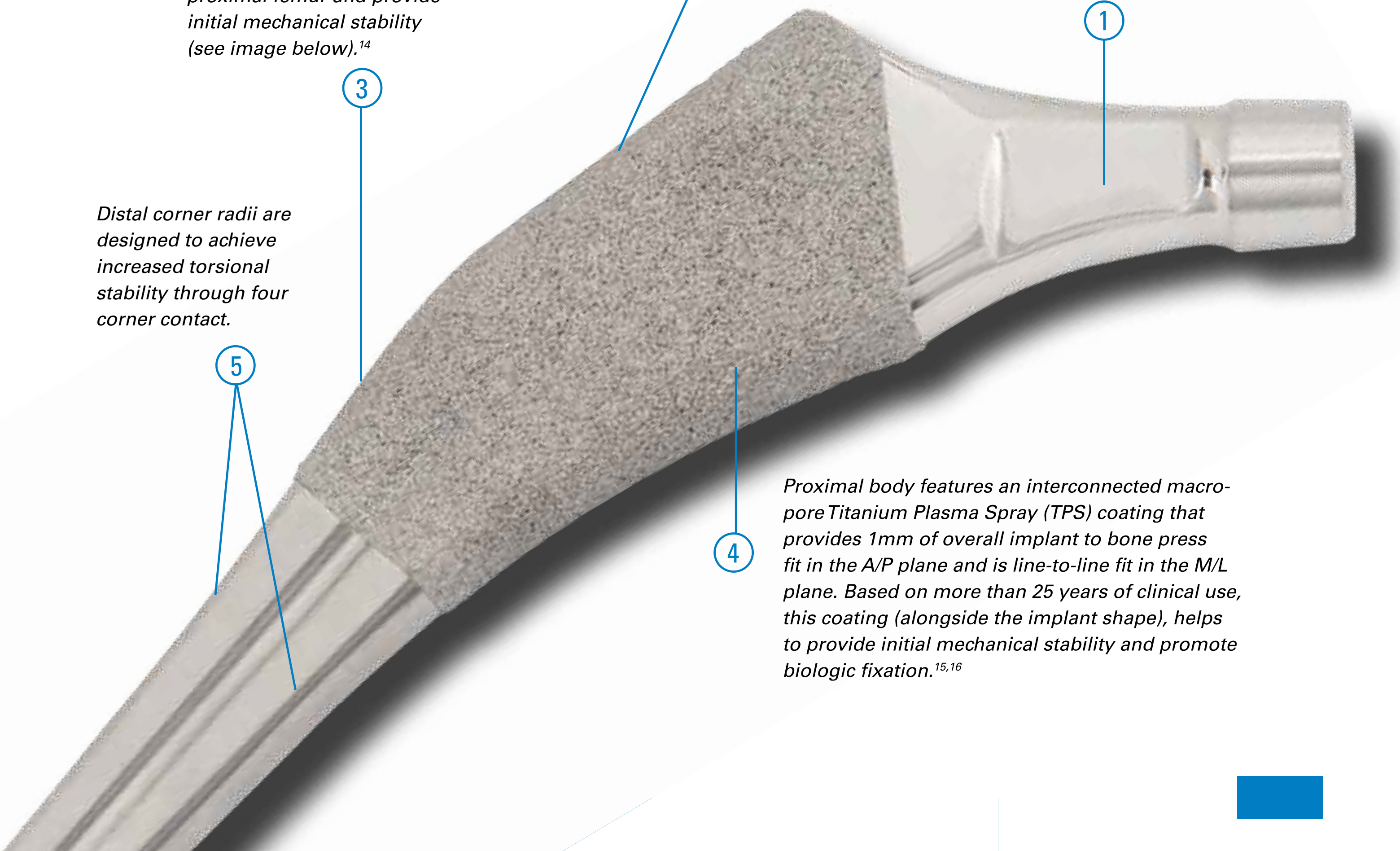
1. *The Alteon Tapered Wedge features a highly polished neck cross-section that is minimized on the medial aspect to increase range of motion, decreasing the chance of post-operative dislocation, while material on the lateral side is maintained for strength.[13]*

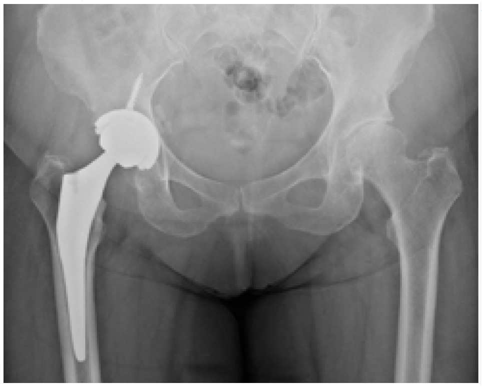
2. *Low profile lateral shoulder allows for ease of insertion when implanting the stem.*

3. *The proximal/distal transitional geometry resulted in a lateral flare feature which is designed to evenly distribute loads in the proximal femur and provide initial mechanical stability (see image below).[14]*

4. *Proximal body features an interconnected macro-pore Titanium Plasma Spray (TPS) coating that provides 1mm of overall implant to bone press fit in the A/P plane and is line-to-line fit in the M/L plane. Based on more than 25 years of clinical use, this coating (alongside the implant shape), helps to provide initial mechanical stability and promote biologic fixation.[15,16]*

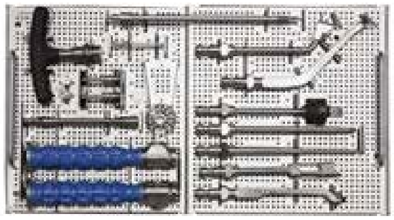
5. *Distal corner radii are designed to achieve increased torsional stability through four corner contact.*



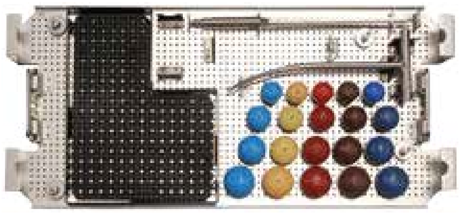


## PLATFORM INSTRUMENTATION

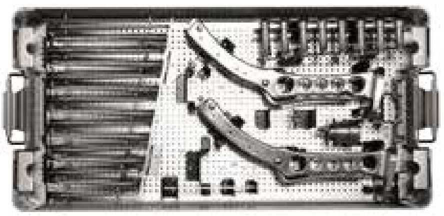
The Tapered Wedge is part of the Alteon family of hip stems. This platform hip system features a set of common femoral instruments that can be used across multiple stems.



**Alteon Common Femoral Instruments (Upper Level Tray)**



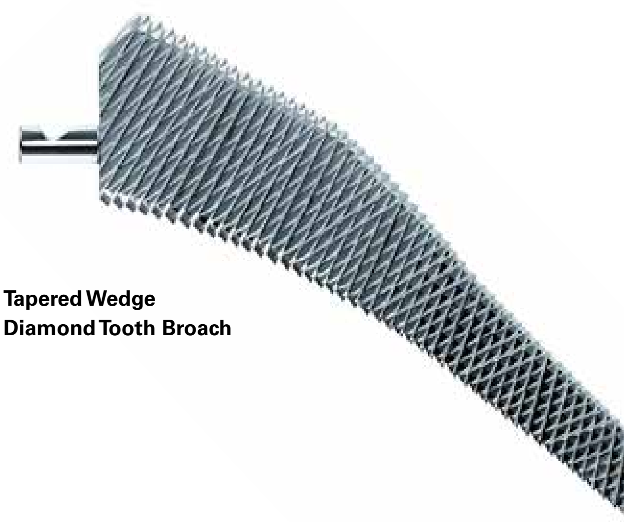
**Alteon Common Femoral Instruments (Lower Level Tray)**



**Alteon Tapered Wedge Instruments – Anterior Approach or all other approaches**

## BROACH DESIGN

- The system uses rasping-style broaches.
- When the Tapered Wedge prostheses is impacted to an axial stopping point, the proximal border of the TPS will be approximately 1.5mm above the final broach.
- The Tapered Wedge brooches are designed to have a press-fit medial to lateral of 0mm only at the midplane (i.e. coronal or frontal) of stem; gradually increasing to 1mm total anterior to posterior. This Broach is designed to eliminate the potential of the distal TPS coating boundary prematurely achieving press-fit and eliminates the possibility of the broach introducing a stress riser as it cuts the femur.



**Tapered Wedge Diamond Tooth Broach**

# Conclusion

The Alteon Tapered Wedge Femoral Stem is a next-generation, single-taper wedge-style stem. By satisfying the surgeon focused design goals, this hip system offers a femoral component which incorporates subtle, yet significant design advancements over first- and second-generation wedge-style stems. The result is a robust system that offers a seamless surgical experience in the operating room.

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*Laboratory and/or animal study tests are not necessarily predictive of clinical outcomes.

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