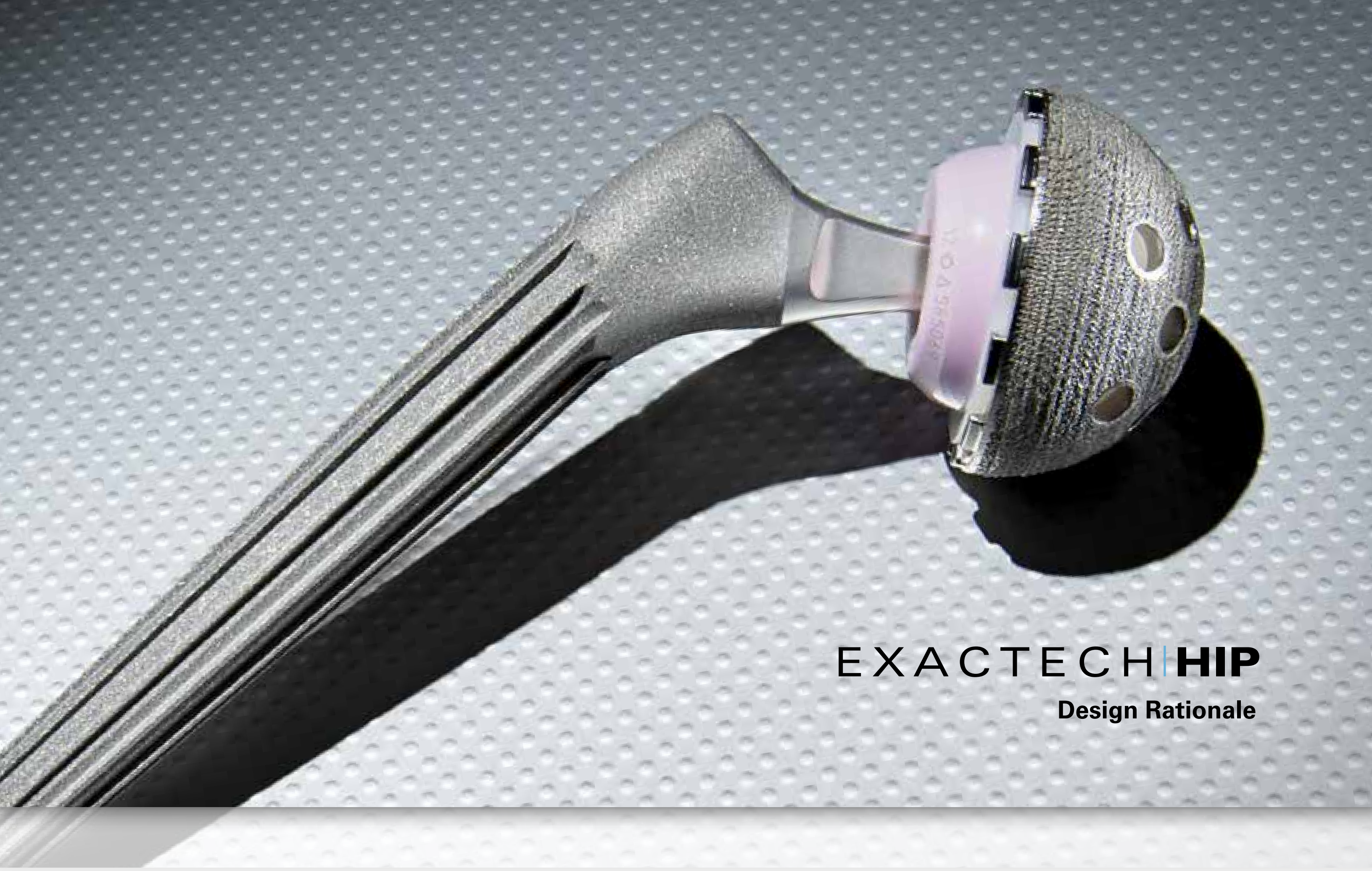

EXACTECH | HIP

Design Rationale

ALTEON®

Monobloc Revision Femoral Stem

ALTEON®

Monobloc Revision Femoral Stem

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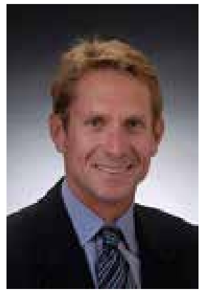
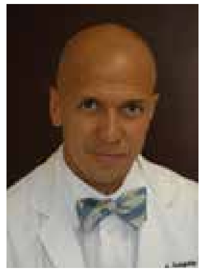
Design Team

Andrew Glassman, MD, is Professor and Chairman of the Department of Orthopaedics and Chief of the Division of Adult Reconstructive Surgery at Ohio State University Wexner Medical Center in Columbus, Ohio. He attended medical school at the Medical College of Ohio, and completed his orthopaedic surgery residency at the Ohio State University; and a fellowship in Adult Reconstructive Surgery at the Anderson Clinic and the National Hospital for Orthopaedics and Rehabilitation in Arlington, Virg.

Michael Kang, MD, practices at the Insall Scott Kelly Institute for Orthopaedics and Sports Medicine in New York, N.Y. He is also Clinical Assistant Professor at NYU School of Medicine. After completing his medical education from Temple University, he received his training in orthopaedic surgery at the New Jersey Medical School. He proceeded to a fellowship in Adult Reconstruction of the Hip and Knee at Stanford University.



Jeff Pierson, MD, practices with Franciscan St. Francis Health in Carmel, Ind. He attended The Johns Hopkins University School of Medicine in Baltimore; his general surgery internship at Northwestern University Medical Center, Chicago; and his orthopaedic residency at the Hospital for Special Surgery. He completed his orthopaedic fellowship in adult hip and knee reconstruction at Harvard University.



Jose Rodriguez, MD, is the Chief of Reconstruction Arthroplasty and the Director of Arthroplasty Fellowship Program at Lenox Hill Hospital in New York, N.Y. Dr. Rodriguez completed his medical school education at Columbia University College of Physicians and Surgeons, and his residency training at the Hospital for Special Surgery. He completed two fellowship programs—one at Lenox Hill Hospital for arthritis surgery and joint reconstruction and the other was the Maurice E. Müller Foundation Fellowship in Hip Surgery at University of Berne, Switzerland for the surgical treatment of fractures.

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

Since its founding in 1985, Exactech has operated with a primary goal of providing implants and services that seek to improve patient outcomes. The Alteon® Monobloc Revision Femoral Stem Design Team set out to study the science behind femoral revision systems and develop a system with optimized implant and instrument features.

This stem is a press-fit, distally fixed, one-piece tapered, splined titanium stem. It incorporates specific philosophies designed to improve surgical experiences and clinical outcomes.

The Monobloc Revision Femoral Stem intends to achieve axial and rotational mechanical stability and operative predictability through a carefully engineered combination of:

- Taper Angle
- Spline Geometry
- Grit Blast Surface Finish
- Reamer and Trial-to-Implant Relationship Predictability

Revision Stem Philosophies

PROXIMAL AND DISTAL FIXATION

Due to the nature of the defects most frequently encountered in femoral revision surgery, proximally-fixed prostheses present challenges to achieving adequate fixation.[1] Distally-fixed implants bypass the damaged proximal bone achieving stability in the isthmus and/or diaphysis distal to any unsupportive defects. Because of their ability to achieve adequate fixation leading to improved clinical outcomes, distally-fixed implants have become the predominant philosophy for treating femoral revisions with proximal defects.

Cylindrical, straight or bowed extensively porous-coated stems and tapered, splined titanium stems are the two predominant distally-fixed stem philosophies.

Cylindrical, Straight Extensively Porous-Coated Stems

Cylindrical, straight or bowed extensively porous-coated stems report good outcomes; however, a large diameter canal with limited opportunity for 4 to 6cm of press-fit fixation has contributed to failures with this philosophy.[1] In some cases, sizing difficulty can occur (specifically undersizing) which can result in a lack of bone ingrowth or femoral fracture.[1] Additionally, cylindrical, straight and bowed extensively porous-coated stems are manufactured from varying materials, some of which have a higher modulus of elasticity than titanium, thus proximal stress shielding and thigh pain can pose a concern.[2,3]

Tapered, Splined Titanium Stems

The Paprosky System for classifying femoral bone stock damage is illustrated in the images to the right *(Figures 1-4)*.[2] Many surgeons feel tapered, splined titanium stems are technically easier to perform, with less risk of femoral fracture, than attempting to obtain 4 to 6cm of scratch-fit fixation with cylindrical, extensively porous-coated stems. According to Harman et al., Type III-A defects are the most frequently encountered defects in femoral revision surgery, with Type II defects being common and Type III-B defects increasing in frequency.[2] A constant variable in the majority of Type II, III-A and III-B defects is extensive metadiaphyseal (proximal) bone loss.[2]

Tapered, splined titanium stems have emerged as a particularly effective option to treat Type II, III-A and III-B femoral defects. This is due to their ability to achieve initial mechanical stability in a larger range of femoral canal sizes and/or proximal defects while promoting proximal bone regeneration.[4-7] Additionally, leg length and offset are better reproduced while experiencing fewer intra-operative fractures.[8]

Figure 1
In Type I, or mild bone stock damage, the cortices of both the metaphysis and isthmus remain intact. Unless the cortical tube is completely devoid of cancellous bone, the situation closely resembles that encountered during primary arthroplasty, and can be treated as such, using the fixation method with which the surgeon is most confident.

Figure 2
In Type II, or moderate bone stock damage, the metaphysis is significantly compromised, yet the isthmus remains intact. In the majority of published reports, Type II bone stock damage is the most commonly encountered. When the metaphysis is significantly damaged, proximally porous-coated stems cannot be relied upon to provide for long-term fixation by bone ingrowth.

Figure 3
In Type III (severe) bone stock damage, both the metaphysis and the isthmus are damaged. Type III cases can be further categorized:

- Type III-A: Those with four or more centimeters of remaining structurally sound bone in the isthmus.
- Type III-B: Those with less than four centimeters of remaining bone.

Figure 4
In Type IV bone stock damage the isthmus has been functionally obliterated.

MODULAR AND MONOBLOC STEMS

The first tapered, splined titanium stem designs were monobloc in nature. Early results included subsidence rates as high as 20 percent.[1] These initial results were attributed to undersizing of the stems during the learning curve, a relatively small taper angle, and seating of the implant at a level which corrected for leg length and offset, but not necessarily axial stability.[1]

In an effort to achieve stability and recreate hip biomechanics, modular components were designed. Modular systems have become the predominant revision philosophy, mainly because they allow for intra-operative flexibility while recreating the appropriate head center of rotation (COR), in addition to attaining mechanical stability. The COR is recreated by first preparing the distal stem, then assembling a proximal body that results in the desired leg length, offset and version. While helpful for recreating biomechanics, the two-piece assembly results in a modular junction that is susceptible to corrosion at the interface and stem junction fractures. Modular stems are also usually bulkier proximally (to accommodate the modular junction) than monobloc stems, which can make extended trochanteric osteotomy repair more difficult, and may lead to an increased likelihood of ETO non-union and escape. When selecting a revision hip prosthesis, the surgeon must decide on a case-by-case basis whether a modular or monobloc implant design is appropriate.

ALTEON MONOBLOC REVISION FEMORAL STEM

The Alteon Monobloc Revision Femoral Stem combines the positive attributes from these revision stem philosophies, resulting in a tapered, splined titanium monobloc stem which can be used to treat the most common types of femoral defects. Through carefully designed instrumentation, this system has the ability to reproduce the COR location without the need for modularity.

Tapered, Splined Titanium Stem Success

Tapered, splined titanium stems have reported successful clinical outcomes. The Zimmer Wagner SL Revision® Hip *(Figure 5)*, Zimmer ZMR® *(Figure 6)* and LINK® MP® Reconstruction Prosthesis *(Figure 7)* are devices that contain several of the major design features chosen for the Alteon Monobloc Revision Femoral Stem *(Table 1)*. These stems have long-standing clinical histories with many publications documenting their survival rates.[6,9-13]

Table 1: Clinical Success Literature

Device	Authors	Survivorship
Zimmer Wagner SL	Regis et al.[6]	Reported 92 percent survivorship at 15.8 years.
Zimmer Wagner SL	Ferruzzi et al.[9]	Reported 99.4 percent survivorship at 6.8 years.
Zimmer ZMR	Munro et al.[10]	Reported 94 percent survivorship at five years.
Zimmer ZMR	Ovesen et al.[11]	Reported 94 percent survivorship after two to seven years.
LINK MP	Kwong et al.[12]	Reported 97.2 percent survivorship at 3.3 years.
LINK MP	Weiss et al.[13]	Reported 98 percent stem survivorship at five years.

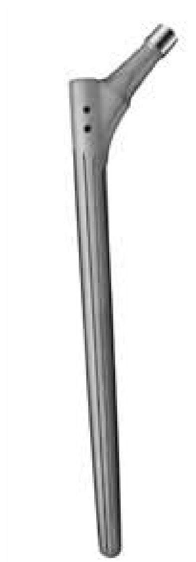


Figure 5
Zimmer Wagner SL®

Figure 6
Zimmer ZMR®

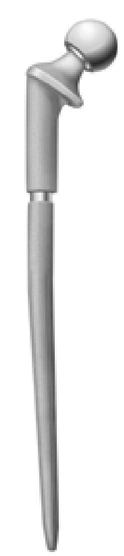


Figure 7
LINK® MP®

Unmet Clinical Needs

IMMEDIATE AND LONG-TERM CENTER OF ROTATION RELIABILITY AND STABILITY

The primary goal of revision hip arthroplasty is to implant a construct that will have not only initial, but long-term mechanical stability. Stem subsidence of tapered, splined titanium revision stems was identified as an opportunity for improvement with non-modular and modular versions reporting subsidence rates of 15 to 20 percent and zero to 43 percent, respectively.[14] Table 2 includes literature regarding stem subsidence. Significant stem subsidence frequently results in a loose stem without osseointegration and, even if osseointegration occurs, results in an adverse change in the COR, leg length, hip stability and kinematics of the reconstruction.

Recreating the COR and ultimately hip biomechanics is targeted secondary to achieving immediate and long-term mechanical stability. The system instrumentation, implant design and scope all can influence how well the surgeon is able to restore the COR.

The surgeon design team and engineering team identified design goals for both the implants and instruments which focused on providing intra-operative and long term COR reliability and stability. Contributing variables were systematically studied and evaluated, resulting in a robust solution to the clinical need.

Table 2: Subsidence Literature

Device	Authors	Subsidence Results
Zimmer Wagner SL	Bohm & Bischel[15]	Reported an average of 5.9mm subsidence, with 26 hips exhibiting more than 10mm of subsidence.
Zimmer Wagner SL	Regis et al.[6]	Reported subsidence of 10 to 30mm in eight of 41 stems (19.5 percent), resulting in two re-revisions.
Zimmer Wagner SL	Grunig et al.[16]	Reported subsidence greater than 10mm in 18 percent (six patients) of stems, resulting in three re-revisions.
Zimmer ZMR	Van Houweling et al.[17]	Reported subsidence in seven of 48 stems, with an average of 12.3mm subsidence.
LINK MP	Park et al.[18]	Reported subsidence in five of 59 stems, with three re-revisions resulting from subsidence of 10-20mm or more.
LINK MP	Rodriguez et al.[3]	Reported subsidence in four of 64 stems (6.2 percent) of less than 5mm (two stems) and 5 to 10mm (two stems).

Design Goals

The combination of the surgeon design team's considerable experiences, their shared collaboration, and the current unmet clinical needs led to the creation of the Alteon Monobloc Revision Stem – a press-fit, distally fixed, one-piece tapered, splined titanium stem. The following design goals are the basis for the design inputs of this product:

- **Achieve stable fixation in a wide variety of bone deficiencies and deformities without the need for modularity**
- **Achieve stable fixation and recreate hip biomechanics with less complexity**
- **Develop reamer and trial-to-implant relationship predictability**

Implant Design Features

3.5° TAPER ANGLE
(Figure 8)

The Zimmer Wagner SL and LINK MP have long-term clinical success, but experience relatively high rates of stem subsidence.[3,6,15,16,18] The 2° distal taper angle of these two stems and similar taper angles of other currently marketed stems may contribute to stem subsidence negatively affecting the long-term COR reliability and stability.

Minimal research had been conducted on the correlation between taper angle and axial stability, thus the surgeon design team completed a comparative study to better understand. Taper angles of 2.5°, 3°, 3.5°, 4° and 5° were evaluated in a laboratory setting. In the chosen spline design (flat), a 3.5° taper angle was found to optimize axial resistance *(Figure 9)* and taper engagement length and location.[19] This resulted in the desired tactile feedback during reaming of the distal taper. Additionally, the 3.5° distal taper angle is consistent with the largest taper angle currently on the revision stem market (Zimmer ZMR stem) which, aside from the reported fractures of the modular junction, has good clinical results to date.[10,11]

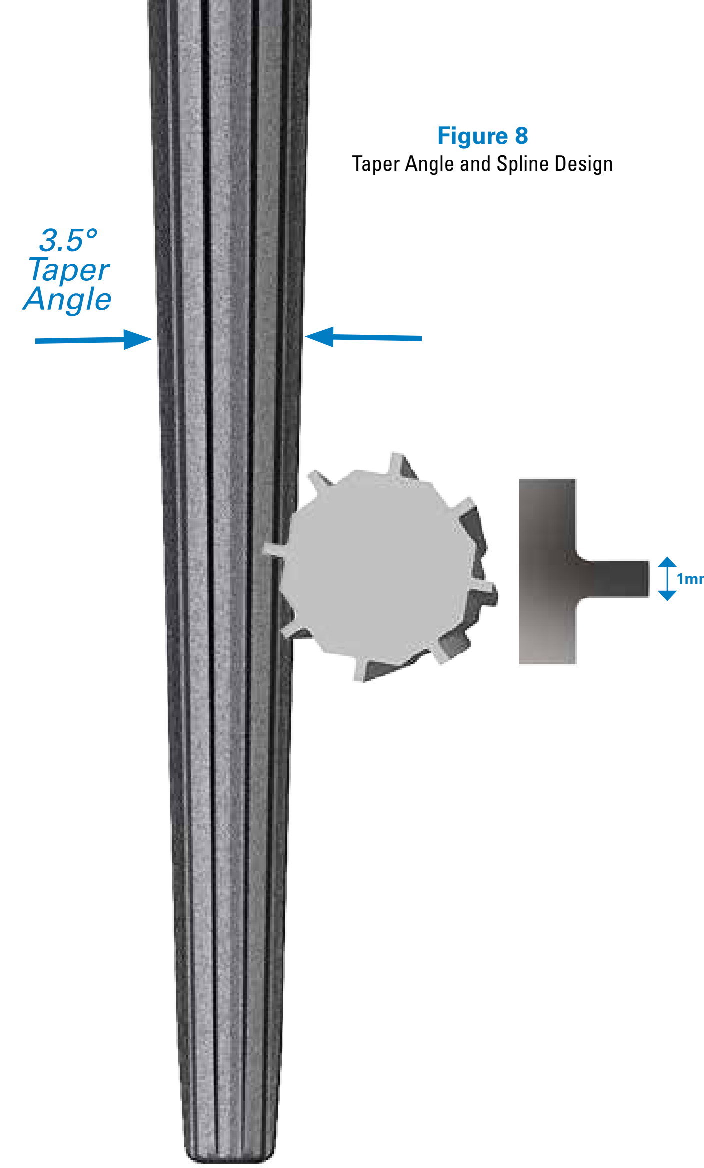


Figure 8
Taper Angle and Spline Design

SPLINE DESIGN

- **Flat/broad (1mm width)** *(Figure 8)*
- **Eight splines (sizes 14-20mm) and 10 splines (sizes 21-30mm)**
- **Minimum 1.5mm height at taper start**

The characteristics of spline geometry, count and width play an integral part in the mechanical stability that resists axial subsidence and rotation. Laboratory testing revealed that a flat/broad design demonstrated greater axial stability *(Figure 9)* and negligible torsional stiffness *(Figure 10)* over a narrow/sharp design.[8]

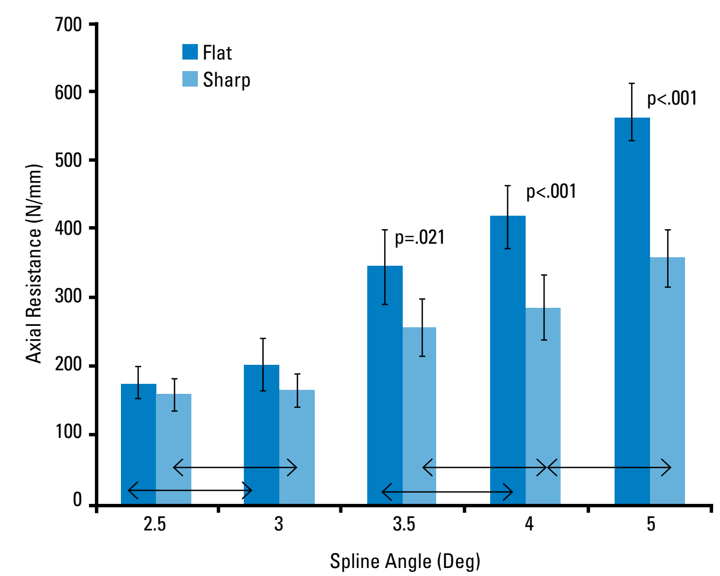


Figure 9
The chart above shows axial stability of different taper angles. The arrows indicate groups of statistically equivalent spline angles within each separate spline design.*

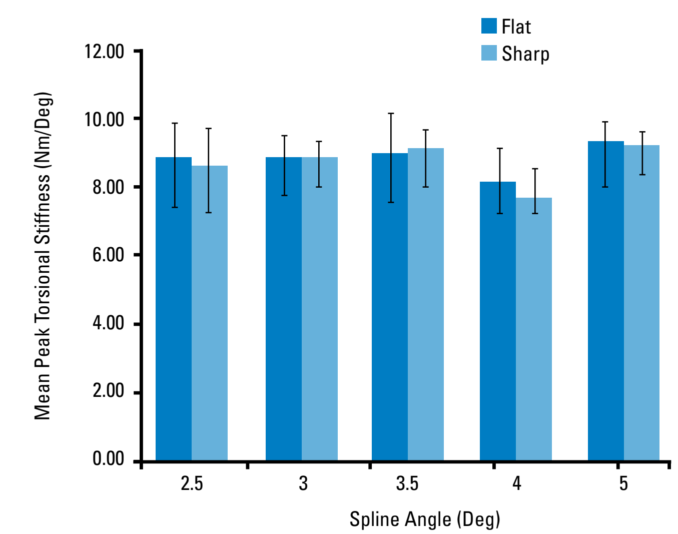


Figure 10
This chart illustrates torsional stiffness of different taper angles.*

**Laboratory test results may not necessarily be indicative of clinical performance.*

Figure 11
Grit Blast Surface Finish

GRIT BLAST SURFACE FINISH

Surface finish average: 8µm (5µm min to 11 µm max)

While the surface finish on the bone apposing surfaces of tapered, splined titanium stems is generally grit blast, the roughness values vary across the designs. The roughened surfaces create a scratch-fit against the bone and provide topography for potential bone ongrowth *(Figure 11)*.[20] After a review of the competitive surface finishes *(Table 3)*, a design input was generated for the surface roughness of the Alteon Monobloc Revision Stems to resemble that of the roughest implant currently available, the clinically successful LINK MP. It is generally understood that increasing the surface roughness of a sample results in a reduction of fatigue life, thus prior to selecting the final parameters, a series of studies were undertaken to better understand the implications of each processing option being considered.[21] The variables were extensively evaluated to ensure that the desired surface roughness allowed for the maintenance of superior mechanical performance.

Table 3: Competitive Surface Finishes

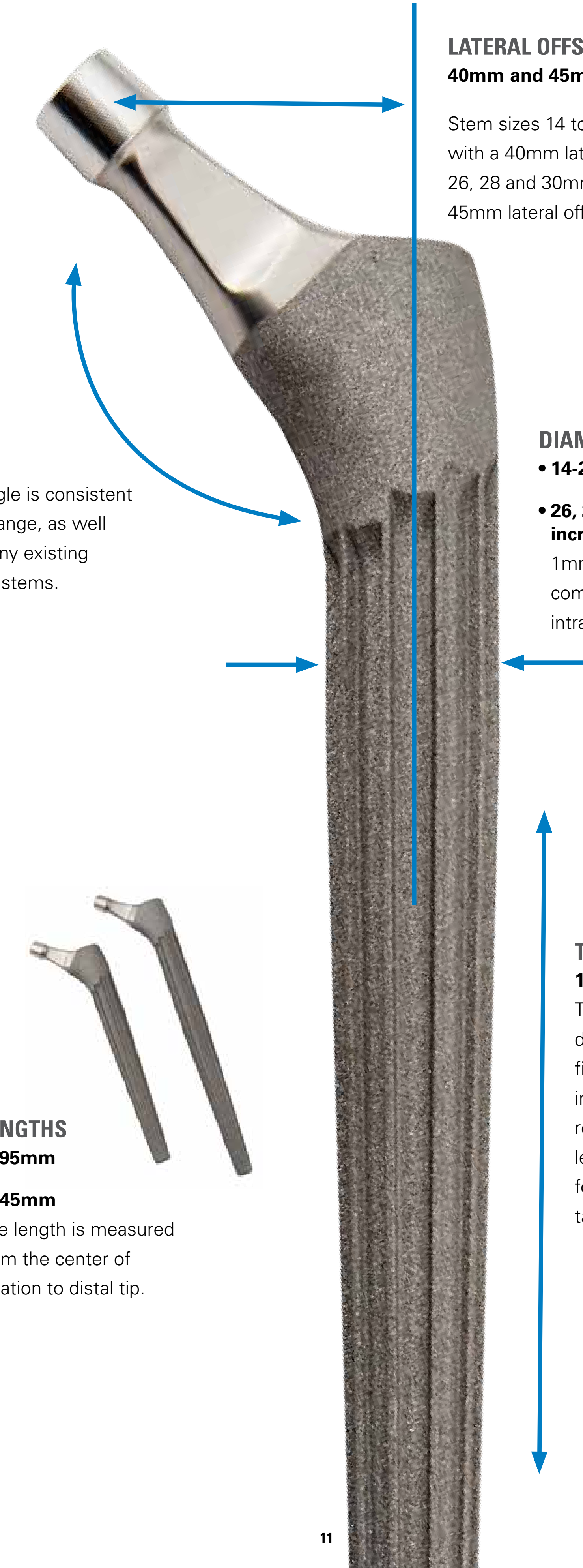
Device	Surface Finish Min (µm)	Surface Finish Max (µm)
Exactech Monobloc Revision Femoral Stem	5	11
Zimmer Wagner SL Revision Stem	NR*	NR*
DePuy RECLAIM Modular Hip Stem	5	5
LINK MP	7	11
Zimmer ZMR Hip Stem	4	7
Stryker Restoration Modular Revision Hip Stem	4.5	5

**Not Reported.*

Because the design goal was based off of the LINK MP, the surfaces of that implant were studied to understand how the roughness was created.** Scanning electron microscope (SEM) images and energy dispersive x-ray spectroscopy (EDS) analysis were used to characterize the elements present. The study confirmed the type of blast media used.

A multitude of different media sizes are available. To better understand the effect of different blast media sizes on Ti-6Al-4V, x-ray diffraction testing was performed to determine the residual stress profiles. It was found that larger medias create less favorable surface conditions and an ideal media size was selected for this application. A final study was executed in order to evaluate the chosen media when applied at different pressures. These studies resulted in a proprietary combination of blast media size and application pressure that create the desired surface roughness without compromising mechanical integrity.

***Study performed using parts owned by Exactech.*



LATERAL OFFSET

40mm and 45mm

Stem sizes 14 to 24mm are designed with a 40mm lateral offset, and sizes 26, 28 and 30mm are designed with a 45mm lateral offset.

NECK ANGLE

131°

The 131° neck angle is consistent with the market range, as well as identical to many existing Exactech femoral stems.

DIAMETERS

- **14-24mm (1mm increments)**
- **26, 28 and 30mm (2mm increments)**

1mm increments in the most commonly used sizes provide intra-operative flexibility.

LENGTHS

- **195mm**
- **245mm**

The length is measured from the center of rotation to distal tip.

TAPER LENGTH

107mm

The taper length dimension for a distally-fixed revision stem is important because it represents the maximum length of implant available for distal fixation in the tapered region.

Instrument Design Features

The Alteon Monobloc Revision Stem implants were methodically designed to provide the foundation for immediate and long-term COR stability. In order to achieve immediate (intra-operative) COR reliability, the same rigor was applied to researching, designing and evaluating instrumentation and a surgical technique that satisfied this goal. The outcome was a predictable relationship between reaming depth, trial seating location and implant seating location, ultimately resulting in a system with the potential for immediate and long-term COR reliability and stability.

Figure 12
Tapered Reamer Flute Length

TAPERED REAMING

The Tapered Reamers are designed to prepare the cavity for the distal taper region of the implant. Several designs of tapered reamers were evaluated in a cadaveric study to understand the relationship between flute design and tactile feedback.[19,22,23] Reamers with flutes corresponding only to the distally tapered region of the implants were found to provide the tactile feedback desired by the design team. This configuration provided a more optimal preparation of the distal femoral canal as compared to the others that were evaluated. Because fixation in the taper is the foundation for reproducing the COR, as well as the basis for implant mechanical stability with this philosophy, reamers with flutes corresponding to the distal taper only were selected *(Figure 12).*

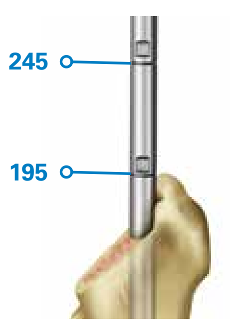


Figure 13
Center of Rotation Grooves

A first step in COR reliability is generating a reference point either at the desired COR or at a known distance from it. The grooves on the tapered reamers correspond to the trial/implant head COR locations, and when sufficient proximal bone exists, the bone can be marked adjacent to the grooves as a reference point *(Figure 13).* Proximal bone loss and/or removal of such bone through an extended trochanteric osteotomy (ETO) frequently occurs during revision surgery, thus eliminating the ability to create a reference point adjacent to the head COR. For this reason, a referencing guide was designed to assemble to the tapered reamers to provide additional landmarks distal to the head COR. These assist the surgeon in identifying where the future trial and implant are expected to seat *(Figure 14).*

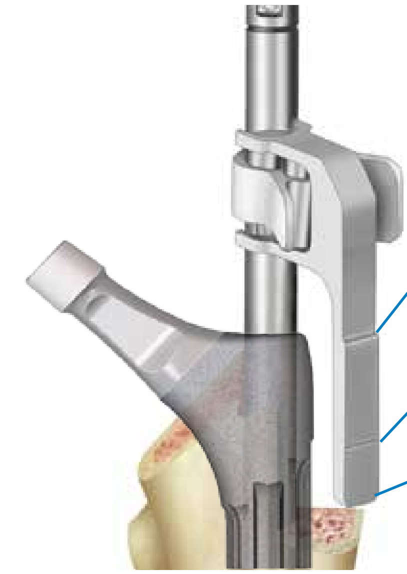


Figure 14
Tapered Reamer Referencing Guide

TROCHANTERIC REAMING

The trochanteric reamers were created to maintain the desired press-fit against the cylindrical region of the implant, while relieving trochanteric bone that may hold the stem in three-point fixation *(Figure 15).* This significant step in the surgical technique ensures distal taper preparation and engagement occurs reliably and reproducibly creating the foundation for a consistent trialing system.

Figure 15
Trochanteric Reaming

TRIALING

Trialing is a critical step of the operative technique to ensure the desired offset and leg length are achieved prior to implanting the final device. This process can be more complex in revision cases due to the severity and breadth of defects present. In addition to seating at an accurate and reproducible location, the trials were designed to achieve both axial and rotational stability. In order to provide confidence that full mechanical stability has been achieved at the desired level, a final input was that the implants should not seat distal to the location predicted by the stem trials.

These goals were satisfied with trials that contain the same features as the implants, but with a slightly undersized outer geometry to prevent the situation in which the implant seats more distally than the trial. The result, which has been confirmed in simulated clinical settings, is a system in which the implants reliably seat 2 to 4mm proud of the predicted location.[22-24]

Radiographic Outcomes

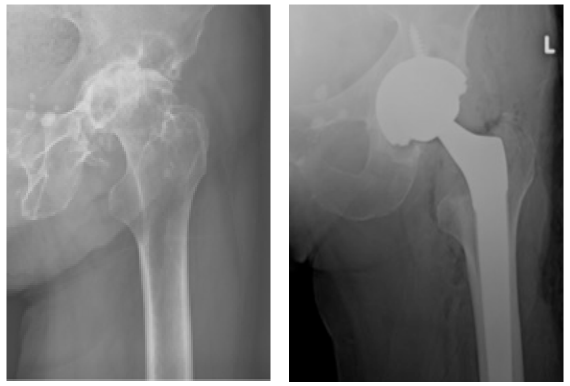


Figure 16
Pre-Operative (Left),
Immediate Post-Operative Radiograph (Right)

CASE 1

A 77-year-old female with severe osteoporosis and a contraindication for cement received the Alteon Monobloc Revision Femoral Stem through a tableless anterior approach *(Figure 16)*. In this complex primary case a 54mm Novation® Crown Cup, 25mm Alteon® Bone Screw, 36mm neutral Connexion® GXL liner, and +0mm Biolox® Delta Head accompanied the 20x195mm Monobloc Revision Stem.

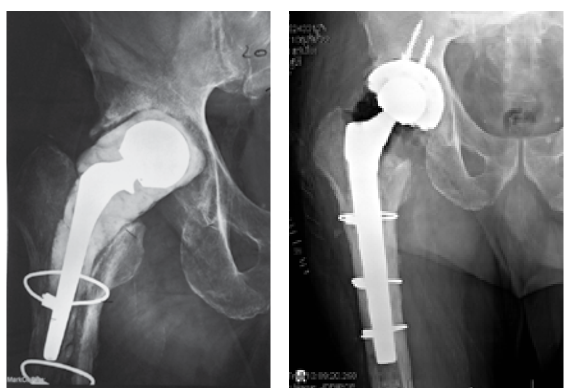


Figure 17
Pre-Operative (Left),
Immediate Post-Operative Radiograph (Right)

CASE 2

A 66-year-old male with an infected primary hip implant received the Alteon Monobloc Revision Femoral Stem through the posterior approach as a part of a two-stage revision *(Figure 17)*. In this case a 62mm Multi-Hole InteGrip® Shell, two Alteon Bone Screws, a 36mm lipped Connexion GXL liner and a -3.5mm cobalt chrome femoral head accompanied the 24x195mm Monobloc Revision Stem.

CASE 3

A patient with a pathological neck fracture received the Alteon Monobloc Revision Femoral Stem through a posterior approach *(Figure 18)*. In this case a 44mm Novation Crown Cup, 25mm Alteon Bone Screw, 28mm neutral Connexion GXL liner, and +0mm Biolox Delta Head accompanied the 14x195mm Monobloc Revision Stem.

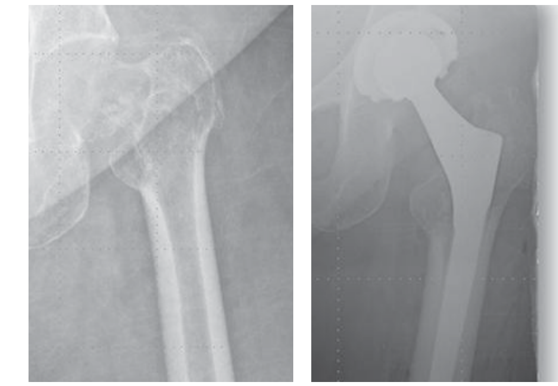


Figure 18
Pre-Operative (Left),
Immediate Post-Operative Radiograph (Right)

CASE 4

A patient with a previously cemented stem received the Alteon Monobloc Revision Femoral Stem through a posterior approach *(Figure 19)*. An extended trochanteric osteotomy was used to facilitate cement removal. In this case a 36mm +0 Biolox Delta Head accompanied the 20x245mm Monobloc Revision Stem.

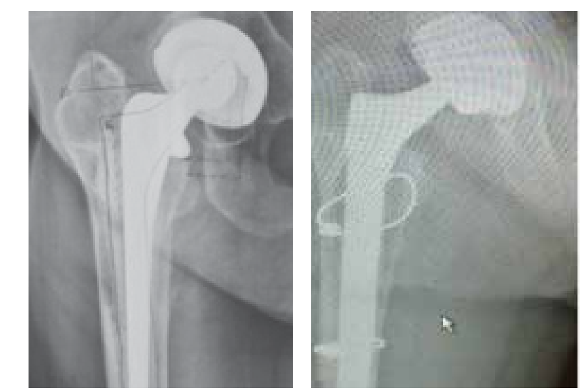
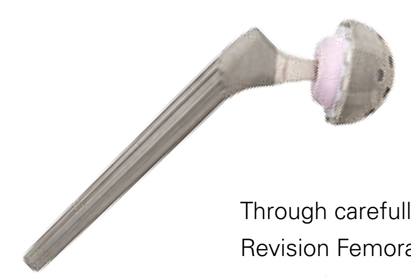
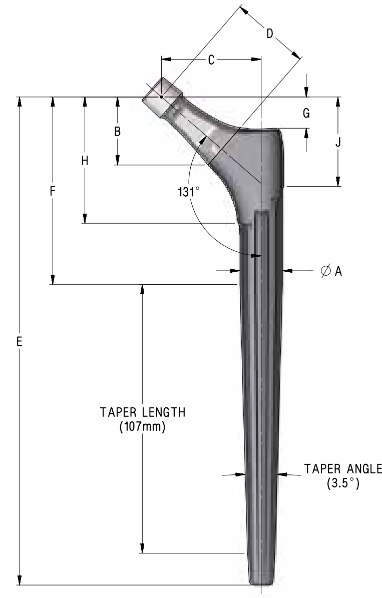


Figure 19
Pre-Operative (Left),
Immediate Post-Operative Radiograph (Right)



Through carefully designed and evaluated implants and instrumentation, the Alteon Monobloc Revision Femoral System satisfies the objective of providing surgeons an improved press-fit, distally-fixed, one-piece tapered, splined titanium stem. This system was designed to create immediate long-term COR reliability and stability in the difficult primary and revision settings. Each feature whether implant, instrument or technique was thoroughly contemplated and scrutinized and what remained is an intentional set of design attributes that comprise this system.

System Specifications



+0mm Femoral Head Offset & Length

A Size/Diameter (mm)	B Neck Height (mm)	C Lateral Offset (mm)	D Neck Length (mm)	E COR to Tip Length (mm)
14-15	27.3	40	36.8	195 & 245
16-20	27.4			
21-24	29.0			
26,28,30	30.6	45	40.6	

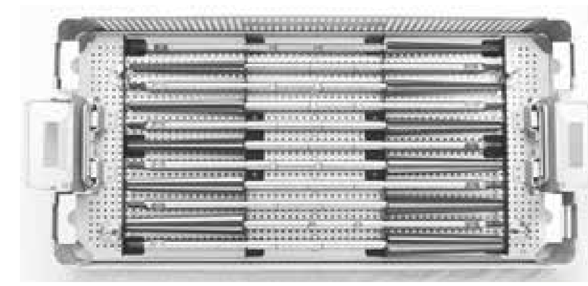
+0mm Femoral Head Landmark Measurements

E COR to Tip Length (mm)	F Taper Start Point (mm)	G COR to Lateral Shoulder (mm)	H COR to Medial Spline (mm)	J COR to Lateral Spline (mm)
195	75	12.7	50	36.5
245	125			

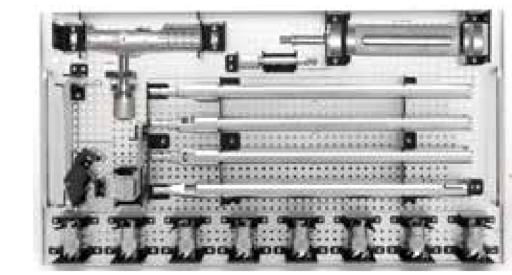
Femoral Head Offset & Length Differences

Head Offset (mm)	ΔB Neck Height (Leg Length) (mm)	ΔC Lateral Offset (mm)	ΔD Neck Legnth (mm)
-3.5	-2.3	-2.7	-3.5
All differences measured from a +0mm Femoral Head			
+3.5	2.3	2.6	3.5
+7	4.6	5.3	7.0
+10	6.6	7.5	10.0

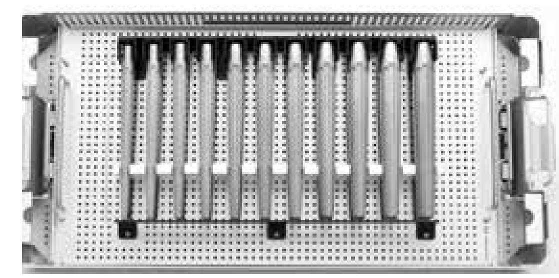
Alteon Monobloc Revision Instrumentation



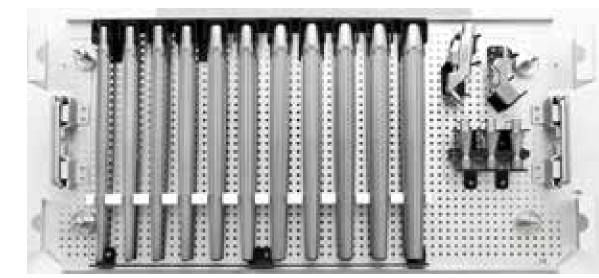
KIT-1401 Alteon Monobloc Reamer Kit
(Lower Level Tray)



KIT-1401 Alteon Monobloc Reamer Kit
(Upper Level Tray)



KIT-1403 Alteon Monobloc Trial Kit
(Lower Level Tray)

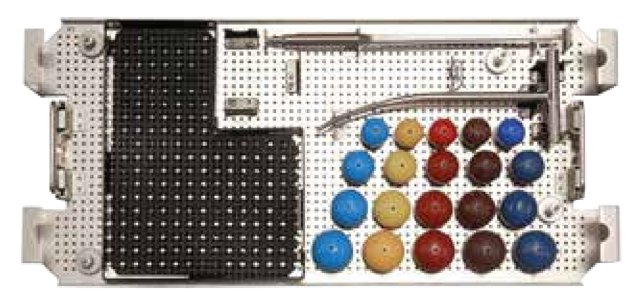


KIT-1403 Alteon Monobloc Trial Kit
(Upper Level Tray)

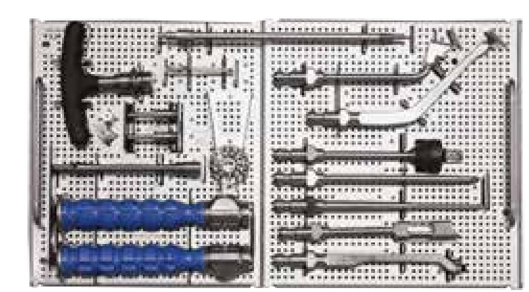
Optional kits are available for sizes 26, 28 and 30mm: OPT-1400 (Implants) and OPT-1401 (Instruments).

Platform Instrumentation

The Revision Monobloc System 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.



KIT-1003 Alteon Common Femoral Kit
(Lower Level Tray)



KIT-1003 Alteon Common Femoral Kit
(Upper Level Tray)

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