



EXACTECH **HIP**
Design Rationale

ALTEON[®]

Neck Preserving Stem



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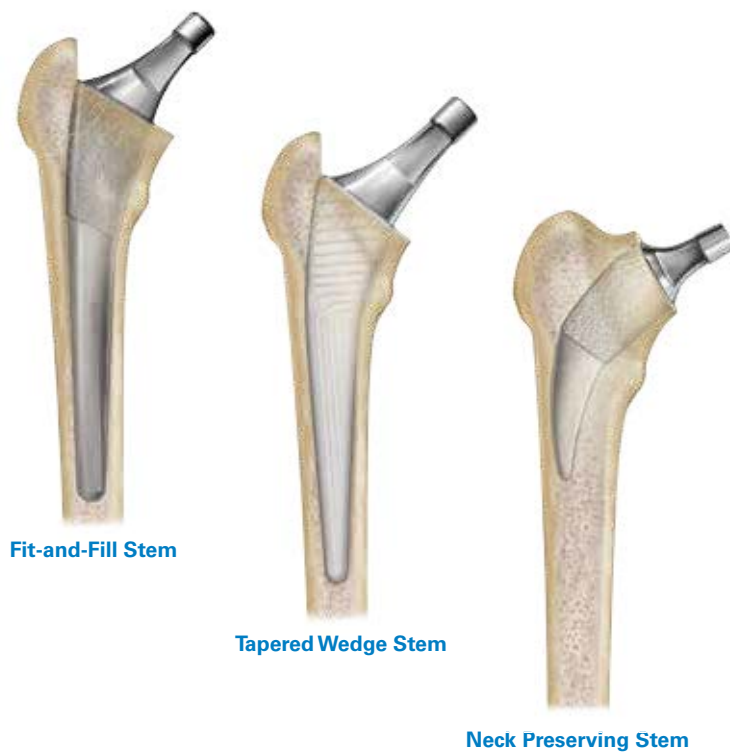
The word “Alteon” is derived from the Latin word “altus” meaning “high,” denoting Exactech’s high performance, next generation hip system. This system is designed to deliver a reproducible, efficient and predictable clinical experience.

Design History and Evolution of the Neck Preserving Stem

Short femoral stems for total hip arthroplasty (THA) have garnered increased popularity over the last decade due to promising short-term clinical and biomechanical success. Initial findings support claims that metaphyseal fixed short stems preserve proximal bone and neck length facilitating future revision THA if needed, reduce stress shielding by loading the femur proximally leading to improved periprosthetic bone density, are less likely to cause thigh pain due to the absence of diaphyseal loading, and allow for less invasive surgical techniques due to a shorter stem length.^{1,15-17}

There are a number of advantages that justify the design and clinical usage of short stems:

- Elimination of femoral proximal/distal mismatch
- Preservation of proximal bone¹⁵
- Facilitation of less invasive surgical exposure
- Less invasive surgical violation into the femoral canal
- Less violation into the trochanteric bed
- Reduction of stress shielding¹⁶
- Reduction of thigh pain¹⁶
- Less instrumentation



The use of short stems is growing. Initial short and mid-term follow up studies from a number of these stems suggest that stable, durable fixation and excellent clinical outcomes can be achieved. As a result, a large number of short stem designs are available.

SUMMARY OF SUCCESS

Recent literature on the revision-free survival rates for modern hip implants have shown remarkable success, with 10-year survival rates of 100 percent for a variety of press-fit, uncemented femoral stem designs at a mean time of 8.2 years from surgery.² The table below highlights implant survivorship of several short stem designs.

Author	Stem Design	Stem Type	Type Name	# of Studies	# of Hips	Aseptic Survivorship of Stem†
McMinn et al.	BMHR	1b	femoral neck only	3	251	99.5% @ 2.8 yrs
Waller	Silent Hip	1b	femoral neck only	1	15	100% @ 2.0 yrs
Morrery et al.	Mayo	2A	calcar loading, trapezoidal	7	503	98.6% @ 5.1 yrs
Wittenberg et al.	Metha	2A	calcar loading, trapezoidal	6	548	99.4% @ 2.9 yrs
Ettinger et al.	Nanos	2B	calcar loading, rounded	1	72	99.8% @ 5.2 yrs
Kendoff et al.	CFP	2B	calcar loading, rounded	14	1394	99.3% @ 6.3 yrs
Ender et al.	CUT	2B	calcar loading, rounded	8	651	92.9% @ 5 yrs
Jerosch et al.	MiniHip	2B	calcar loading, rounded	1	180	98% @ 2.1 yrs
Budde et al.	Custom	2B	calcar loading, rounded	1	15	93.4% @ 3.1 yrs
Carlsson et al.	GOT	2C	calcar loading, threaded	1	53	96.3% @ 3.0 yrs
Ishaque et al.	TPP	2D	calcar loading, thrust plate	16	1980	96.6% @ 5.4 yrs
Munting et al.	Custom prosthesis	2D	calcar loading, thrust plate	1	48	83.3% @ 5.8 yrs
Kim et al.	Proxima	3	lateral flare calcar loading	5	595	100% @ 4.2 yrs
Santori and Santori	Custom	3	lateral flare calcar loading	1	129	100% @ 8.0 yrs
Patel et al.	Custom	4	shortened tapered	3	294	100% @ 3.7 yrs
Molli et al.	Taperloc Microplasty	4	shortened tapered	1	269	99.6% @ 2.5 yrs

Unmet Clinical Needs

Bone Sparing Resurfacing Prosthesis

Hip resurfacing has fallen out of favor due to the difficulty of placing the prosthesis and concerns with metal-on-metal.



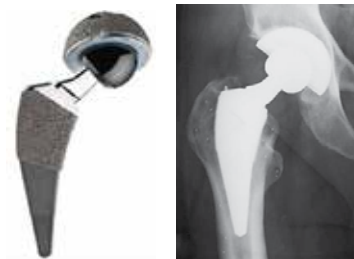
Neck Preserving Prosthesis

Minimal bone resection by preservation of the femoral neck and proximal cancellous bone.



Canal Preserving Prosthesis

These stems are rarely neck-preserving as they often extend up into the upper diaphysis. They are similar to conventional, proximally porous-coated tapered designs with a shorter length and/or reduced distal geometry.



YOUNGER PATIENTS

Osteoarthritis (degenerative arthritis), the most common form of arthritis, affects nearly 21 million people in the United States. This condition that causes “wear and tear” to joint cartilage and develops after years of constant motion and pressure on the joints. As the cartilage continues to wear, the joint becomes inflamed and can result in unbearable pain and decreased range of motion.

Younger patients typically are seeking to regain their active lifestyle. There is a growing subset of active patients known as baby boomers, who in the past were often thought of as “too young for a hip replacement.”

BONE SPARING

Several orthopaedic companies have introduced new implant designs in the market that are “canal preserving,” meaning these stems were merely shortened from conventional design. A more conservative option was thought to be femoral resurfacing, which preserves the head/neck region of the femur. McMinn stated, “The best indication for hip resurfacing is a young active patient with severe hip arthritis, good hip morphology and reasonable bone quality.”³ Thus far resurfacing has been a cemented procedure and has predominately been coupled with metal-on-metal articulation. Resurfacing procedures have fallen out of favor recently for several reasons, including the difficulty of placing the prosthesis as well as concerns with metal-on-metal articulations.⁴

NECK SPARING ARTHROPLASTY

A “neck-sparing” prosthesis is not a new concept, but is one that has been gaining in popularity. This press-fit prosthesis has similar design materials and concepts compared to traditional prosthesis, but it preserves more native bone in the femoral neck of the patient during femoral preparation. This idea shares many similarities to resurfacing with the goal to allow placement of an implant while leaving a viable option for revision if necessary.⁴

The femoral neck is cut higher than traditional implants. These prostheses have a press-fit proximal porous coating for biological fixation and a modern-bearing surface that can be utilized by the surgeon. As stated by Rubin, this novel design saves a significant portion of native host bone and will lead to theoretically easier revision surgery if necessary.^{3,4}

Freeman, Townley, Whiteside and Pipino have all advocated saving the femoral neck since the 1980s. Freeman, who wrote the classic article "Why Resect The Neck?," is referred to as the "Godfather" of neck retention.⁵

His stem retained the femoral neck but was a conventional length straight stem that engaged both the metaphysis and diaphysis. The original stem was designed for cemented fixation, but later modified to introduce a cementless style.

Townley and Whiteside also designed conventional length straight stems that retained the femoral neck, but in 1979 Professor Pipino first advocated the short curved neck sparing stem that could be stabilized by fit-and-fill of the femoral neck as a cementless press-fit stem.

His Biodynamic hip prosthesis, a collared press-fit stem, was implanted from 1983 to 1996, until it was replaced by the modified LINK® CFP Hip Prosthesis Stem. Pipino reported outstanding results of his stem design, with 97 percent satisfactory radiographic results and an implant survival rate of almost 100 percent at 25 years.⁶



Freeman Stem

This stem retained the femoral neck but was a conventional straight stem.

Images courtesy of JISRF & RR archives

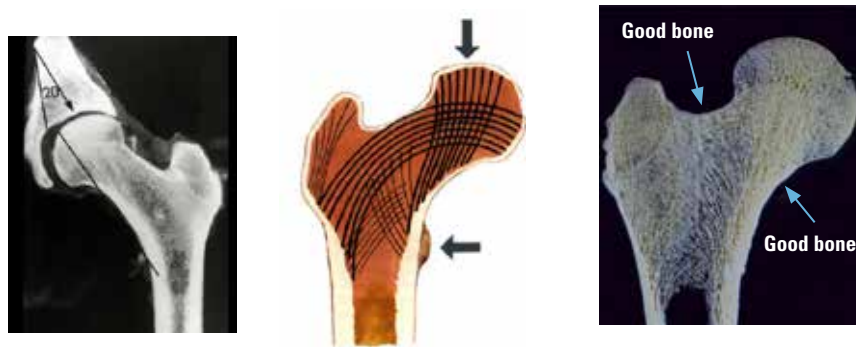


Biodynamic Hip

CFP Hip

Exactech Implant Design Philosophy for Neck Preserving

It is important to maintain blood supply of the proximal femur and support the preservation of these load bearing bone structures.⁷ The femoral neck, along with the adjoining medial aspect of the femur in the calcar region, show the strongest structure with a high load capacity to support the stem.⁴



Images courtesy of JISRF & RR archives

NECK PRESERVING

Why save the femoral neck?

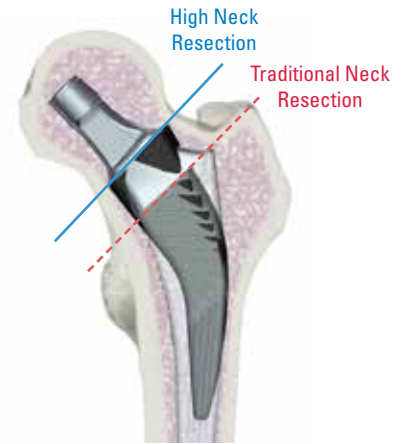
The natural trabecular pattern of the bone and trabecular orientation in the femoral neck provide support against the natural functional loading. Femoral neck retention reduces both torsional and bending moments (forces) at the stem/bone interface. This creates the necessary functional stability of the individual bone areas within the proximal femur.⁴

In accordance with Wolff's Law, the reduction of stresses relative to the natural situation would cause bone to adapt itself by reducing its mass, either by becoming more porous (internal remodeling) or by getting thinner (external remodeling).

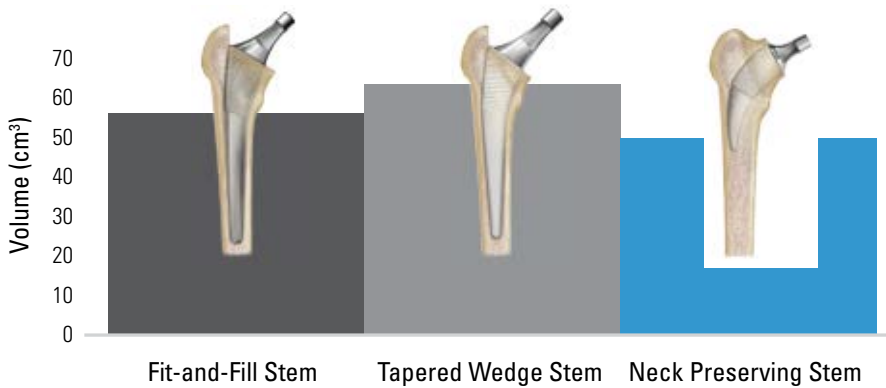
Mihalko’s work showed the importance of replicating the native anatomy with a cadaver study suggesting the level of the femoral neck cut and the anatomic shape of the bone dictate implant positioning of a short metaphyseal stem. Surgeons who use a short metaphyseal stem need to realize the importance of a proper femoral neck cut to restore anatomic parameters.⁸

The Neck Preserving Femoral Stem is designed for preserving and maintaining the maximum amount of proximal femoral bone, while providing initial stability and promoting biologic fixation. In order to achieve the design intent, the Neck Preserving Femoral Stem incorporates specific geometry that transfers loads to the femur in a pattern consistent with its natural anatomy.

To preserve the maximum amount of femoral neck, the Neck Preserving Femoral Stem was designed to target a 50 degree neck resection (measured off the vertical axis). The design of the Neck Preserving Femoral Stem allows the neck resection to be made at a point that is proximal to the neck resection of most traditional press-fit prostheses.



Neck Cut Comparison

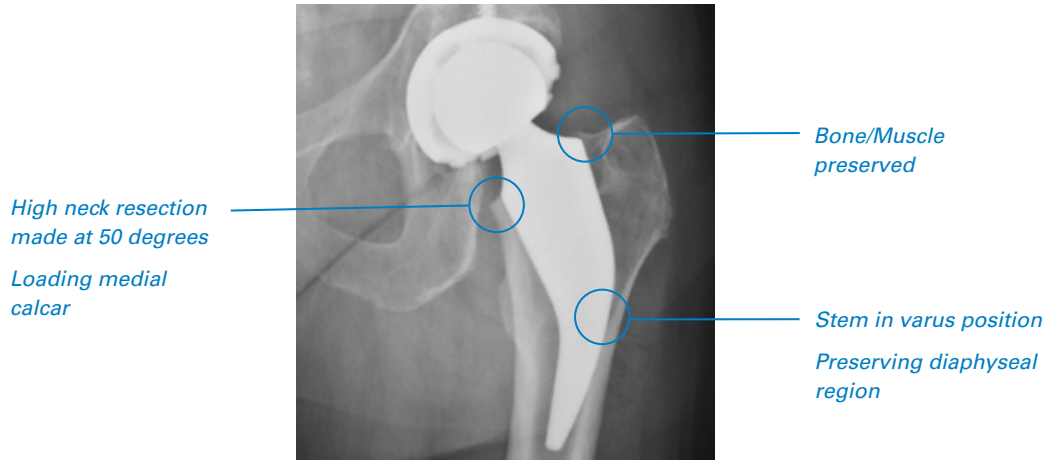


Neck Preserving Stem removes up to 30 percent less bone
In laboratory testing, the Neck Preserving Stem demonstrated a statistically significant amount of bone and femoral neck length preserved compared to Exactech THA stems.

STABILITY

How does the implant achieve its fixation?

The Neck Preserving Stem is collarless, trapezoidal and triple-tapered. Medially the prosthesis will load the calcar. The curved or angulated distal geometry of the stem contacts the proximal lateral cortex, enhancing load transfer laterally, and providing three-point fixation.

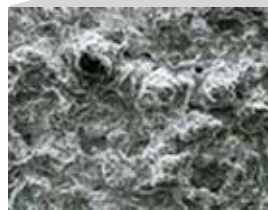


The stem is designed to achieve three points of stability in both the sagittal and coronal plane. Short term results of the Neck Preserving Stem show similar levels of initial stability when compared to traditional stems with improvements made in the amount of bone preserved.¹⁰

This load creates femoral reaction forces which resist rotational moments and stabilize the implant.⁹ The flat medial aspect of the stem is designed for tangential contact of the medial metaphyseal curve to ensure point contact regardless of varus/valgus stem positioning. The medial and lateral radii of the Neck Preserving Femoral Stem were designed to create a favorable bone implant interface while also allowing the largest medial/lateral dimension of the stem to be consistently projected on the anterior/posterior (coronal) radiograph.

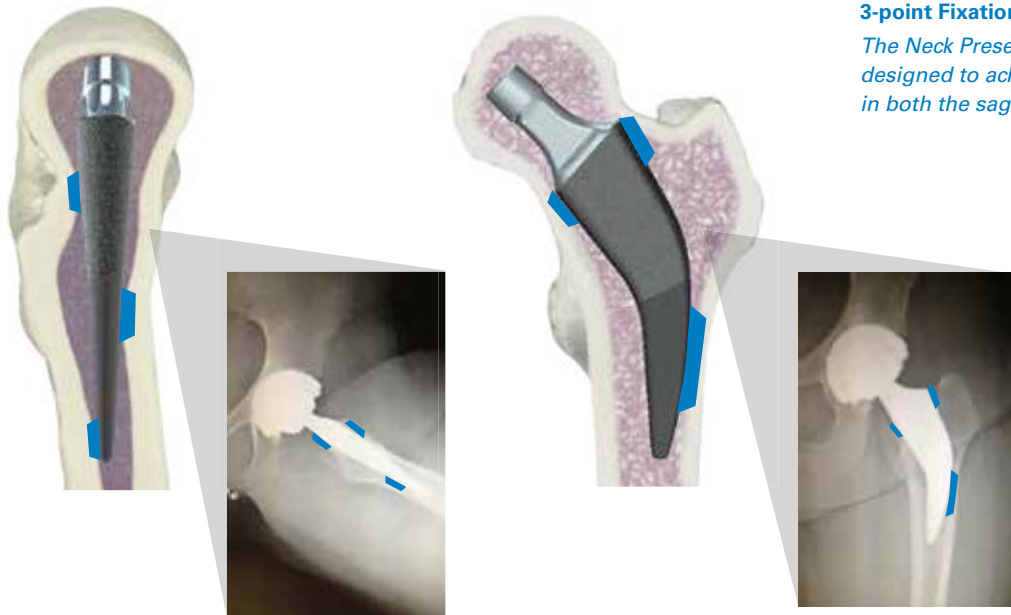
Plasma Spray

Initial mechanical stability, including plasma spray, promotes biologic fixation. In animal testing, biologic fixation was seen in four weeks.^{18,19}



Trapezoidal Design

Triple taper and trapezoidal cross-section which ensure rotational stability with promotes biologic fixation.



3-point Fixation

The Neck Preserving Stem is designed to achieve 3-point stability in both the sagittal and coronal plane.

Surgical Pearls

When implanting the Neck Preserving Femoral Stem, it is important to take into consideration the following surgical pearls:

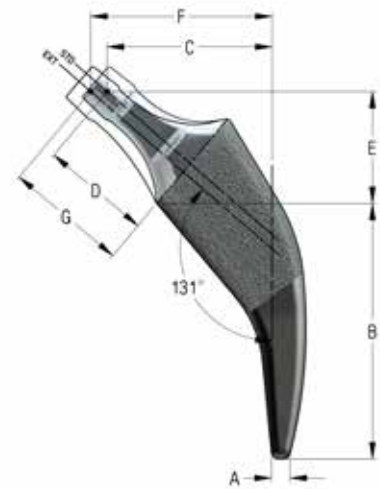
- **Establish Three-point Fixation** – Verify that some point of distal/lateral stem is touching the lateral cortex, then ensure that you have 3-point fixation. Most often this is achieved through both anterior and lateral views, which can be confirmed by radiographic images.
- **High Neck Cut** – Err on the side of a higher neck resection, approximately 50 degrees or close to sub capital. Ideally, the resection should be made approximately at the mid-point of the arch created between the proximal border of the lesser trochanter and the intersection of the femoral head and medial femoral neck. Maintain as much of the proximal/lateral ‘saddle’ as possible, while still allowing the stem to achieve three-point fixation, as this bone may provide additional stability.
- **Find Lateral Cortex** – Utilize a canal finder (t-handle or rasp) to hug the medial side of the resection. This will allow you to find the lateral cortex. Do not lateralize or come from the lateral aspect of the neck resection.
- **Acetabular Reaming** – Acetabular reaming may be more difficult with the extra femoral neck bone present, especially using the Direct Anterior Approach. The surgeon may need to manipulate the leg (flexion or elevation) in order to get proper exposure of the acetabulum. A retractor is included in the instrument set to ‘depress’ the proximal neck inferiorly and protect the femur.

Neck Preserving Stem Growth



How does the implant grow in size?

The stem design features proportional necks for sizes 2-5, which provide consistency between sizes. Sizes 5, 6 and 7 were designed with identical neck lengths and heights to best reproduce the natural anatomy of studied larger femurs.¹³ The stem grows proportionally through the six sizes (2-7). As measured along the calcar plane, each femoral stem grows approximately 3.1mm medial to lateral and approximately 1.4mm anterior to posterior.



STANDARD OFFSET

Size	A M to L tip width (mm)	B Stem Length (mm)	C Lateral Offset with the following head lengths (mm)					D Neck Length with the following head lengths (mm)					E Vertical Offset with the following head lengths (mm)				
			-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10
2	4.3	74	36	39	41	44	46	22	25	29	32	35	23	25	27	30	32
3	4.8	73	40	43	45	48	50	24	28	31	35	38	26	28	30	33	35
4	5.2	73	44	47	49	52	54	27	31	34	38	41	29	31	33	36	38
5	5.7	78	48	50	53	56	58	30	34	37	41	44	32	34	36	39	41
6	7.5	80	50	53	55	58	60	30	34	37	41	44	32	34	36	39	41
7*	8.6	83	53	55	58	61	63	30	34	37	41	44	32	34	36	39	41

EXTENDED OFFSET

Size	A M to L tip width (mm)	B Stem Length (mm)	F Lateral Offset with the following head lengths (mm)					G Neck Length with the following head lengths (mm)					E Vertical Offset with the following head lengths (mm)				
			-3.5	0	3.5	7	10	-3.5	0	3.5	7	10	-3.5	0	3.5	7	10
2	4.3	74	41	44	46	49	51	25	29	32	36	39	23	25	27	30	32
3	4.8	73	45	48	50	53	55	28	32	35	39	42	26	28	30	33	35
4	5.2	73	49	52	54	57	59	31	34	38	41	44	29	31	33	36	38
5	5.7	78	53	55	58	61	63	34	37	41	44	47	32	34	36	39	41
6	7.5	80	55	58	60	63	65	34	37	41	44	47	32	34	36	39	41
7*	8.6	83	58	60	63	66	68	34	37	41	44	47	32	34	36	39	41

EFFICIENCY

The Alteon Neck Preserving Stem achieves efficiency by its offset options, instrument tray design, stem design and broaching technique.

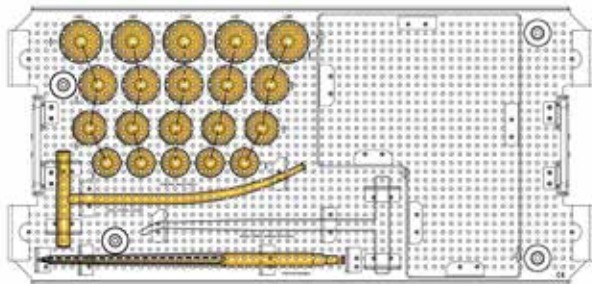
Offset Options

Achieving soft-tissue tension is important for the success of total hip arthroplasty. This system is designed with multiple offset options to provide surgeons with flexibility when matching the patient's native anatomy. The extended offset is a pure lateralized shift of 5mm by shifting the neck medial, which does not increase leg length. This allows for efficiency by not requiring the reassessment of leg lengths intraoperatively.

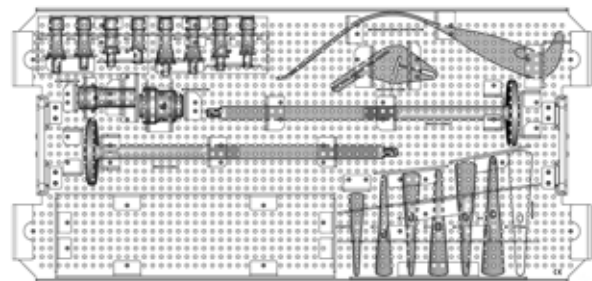
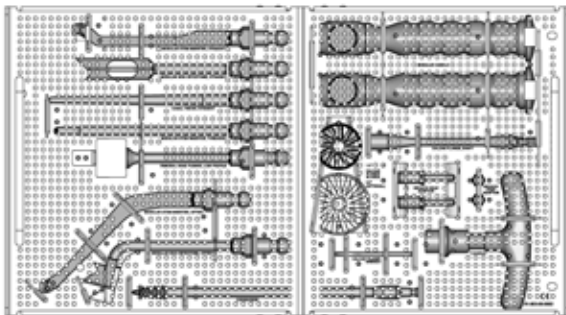


Instrument Trays

The Neck Preserving Femoral Stem 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 stem types.



- Platform stem design, with the ability to switch to other Alteon femoral designs by only changing the broach pan, preoperative or intraoperative.

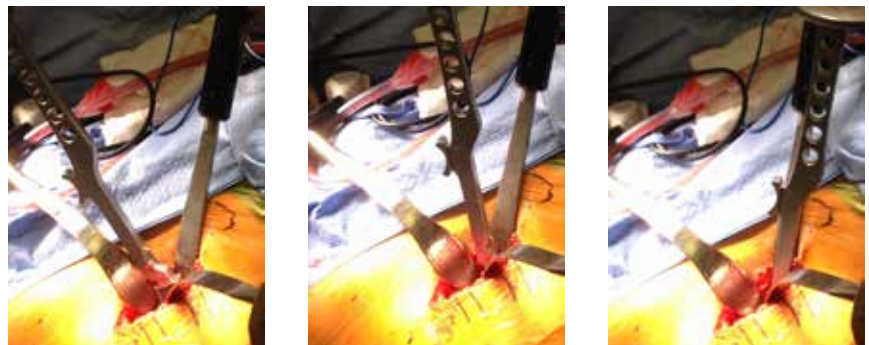
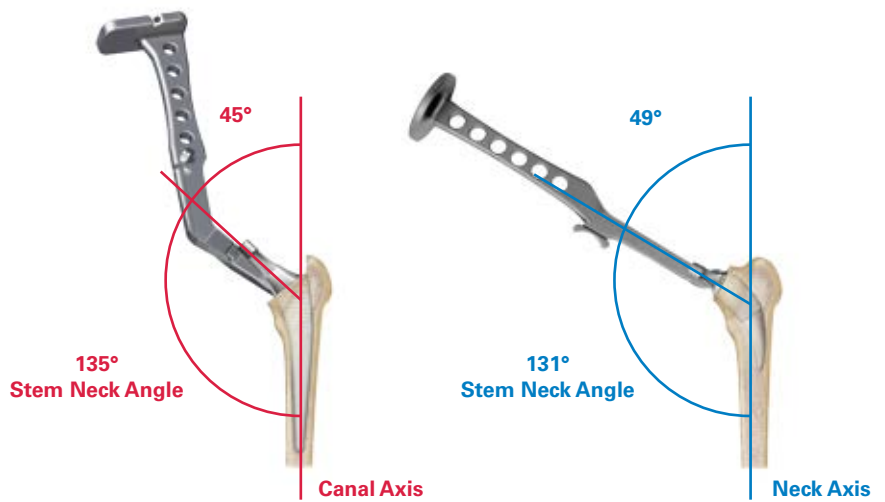




Stem Design and Broaching Technique

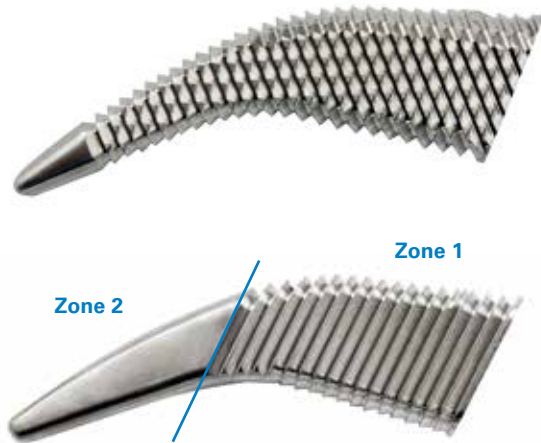
Unlike traditional femoral stems, the Neck Preserving Stem broaches down the femoral neck axis rather than the femoral canal. This design is intended to require fewer soft tissue releases. With curved geometry and broach-only system, the implant is designed to preserve host bone and follow the native anatomy. Variability in internal or external rotation of the femur can result in inaccurate sizing of stems when templating. The stem features medial and lateral radii, which are designed to allow for more consistent projection of M/L width on radiographs despite minor rotational variability. The lateral radius of the implant allows for flexibility in varus/valgus stem positioning.

The geometry of the Neck Preserving Femoral Stem facilitates insertion in low-profile incisions and surgical approaches. Specialized instrumentation was designed to facilitate this. The Neck Preserving Femoral Stem technique allows the broach to “turn the corner” in order to broach down the neck axis. This allows for inherent flexibility in the positioning of the stem, which means fewer sizes are required to cover the patient population.¹¹⁻¹³



Example of Direct Anterior Approach Total Hip Replacement
Broaching down the neck axis.

Alteon Neck Preserving Instruments



Starter Broach

Rasping-style teeth designed for canal entry creates a portal for progressive broaching.

Compaction Broaches (sizes 2-7)

Zone 1

Compaction broaches designed to compress cancellous bone.

Zone 2

Distal matte finish aides in finding the lateral cortex without cutting, which helps to avoid canal perforation.

Conclusion

Primary femoral stems that are on the short side of typical implant systems have enjoyed positive reviews in the literature with no additional complications beyond those of standard-length primary stems. Clinical use of these stems in some cases has been in excess of 25 years.¹⁴

Early clinical results treating osteo/degenerative arthritis in patients with a mean age of 59 years old have been successful with the Neck Preserving Stem, as indicated by improved clinical outcomes using Harris Hip Scores and Oxford Hip Scores. Preservation of the femoral neck has been achieved in the early cases with a mean resection from the lesser trochanter of approximately 27mm. Further clinical studies are ongoing.



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For additional device information, refer to the Exactech Hip System—Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

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