AcuMatch®
INTEGRATED HIP SYSTEM

M-SERIES
Modular Femoral Stem

INTRODUCTION

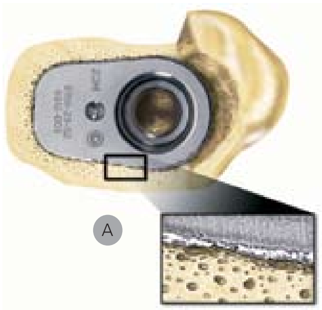
Orthopaedic surgeons face many challenges when performing total hip arthroplasty. Exactech® has developed a product that will effectively meet those challenges with one comprehensive system: The AcuMatch® M-Series modular femoral stem.

The AcuMatch M-Series allows for complete intra-operative customization. This unique three-piece stem offers 100% interchangeability of components, resulting in 33,000+ neck/metaphyseal/stem configurations.

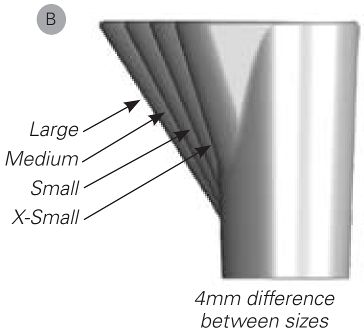
The patented design addresses critical issues of primary and revision hip surgery such as bone loss, leg length, and joint stability. With the freedom to place segments in any rotational orientation, the M-Series enables surgeons to offer restoration, not accommodation, in even the most difficult surgical situations.

ADDRESSING THE ISSUE OF UNPREDICTABLE BONE LOSS

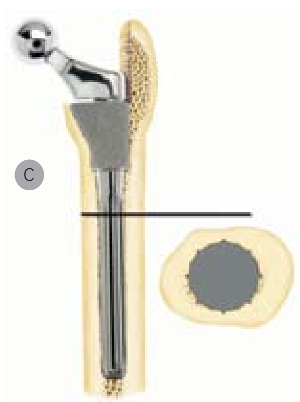
Nothing is routine about revision total hip surgery. It is an art. Frequently, unpredictable bone loss results from retrieval of the previously implanted stem. With the AcuMatch M-Series and its various implant options, managing unpredictable bone loss becomes a less daunting task.



A The metaphyseal segment of the AcuMatch M-Series is designed to address many difficult situations routinely found in total hip arthroplasty. The trapezoidal shape of the metaphyseal segment provides excellent rotational stability while the titanium plasma coating provides an environment conducive to bone ongrowth.



B Each metaphyseal segment is available in diameters of 21mm to 31mm in 2mm increments, each with various flare sizes. There is a 4mm difference between each flare size in the medial-lateral dimension of the component. This increase in flare size allows the surgeon to accurately fit the metaphyseal implant into the available host bone, ensuring that the implant is stable and proximally loading the femur.



C The stem segment features flutes 1.25mm over the nominal size of the implant to increase torsional stability.

Each component can be inserted in any orientation. This results from a patented taper design that allows for anatomical placement of each component.

D Consider, for example, a patient who presents with a lateral femoral bow. Placing the stem in a non-traditional manner is easily accomplished with the AcuMatch M-Series. The distal stem segment is independent of all other segments and its placement is not dictated by neck version.

E A patient with severely deficient bone in the metaphyseal region presents another challenge. In this situation, the metaphyseal segment was rotated so the flare of the implant was lateral instead of medial, resulting in a stable construct.

F Each stem segment is 100% interchangeable with its mating segment, regardless of size. In cases where proximal/distal mismatch is an issue, the smallest stem can be coupled with the largest metaphyseal segment, or vice versa, as needed to address a wide range of bone loss situations.

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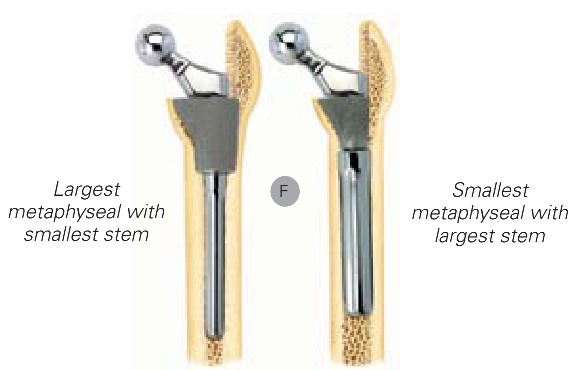

ADDRESSING THE CRITICAL ISSUE OF JOINT STABILITY

Proper restoration of offset ensures joint stability by tightening and tensioning the surrounding muscles and soft tissue. Greater femoral offset after total hip arthroplasty allows both an increased range of abduction and greater abductor strength.[1] Lateralization of the femoral component restores hip biomechanics and significantly decreases polyethylene wear.[2]

Decreased femoral offset is a main contributor to post-operative dislocation of the hip,[3] which occurs in approximately 2% to 3% of total hip arthroplasties.[4] However, when adjusting offset to increase joint stability, leg length is often negatively affected.

Leg length discrepancy following total hip arthroplasty is a common cause of patient dissatisfaction.[5] When trying to achieve joint stability, lengthening of the operated limb can occur.[6]

G H To address the issues of offset and leg length, the AcuMatch M-Series allows the surgeon the unique opportunity to adjust one without affecting the other. This is made possible by offering neck segments in two different offsets, each with a variety of vertical heights.

I Consider the situation where offset is adequate at 41.2mm, but there is an inequality in leg lengths. By adjusting only the vertical height of the neck segment, offset can be maintained while restoring leg length. Conversely, consider the situation where leg length is equal but the joint is unstable. Additional lateralization of the stem must occur to restore proper hip biomechanics and abductor strength but leg length must not be changed. By adjusting to a high offset neck segment, which increases pure offset by 5mm, joint stability can be achieved while leg length remains unchanged.

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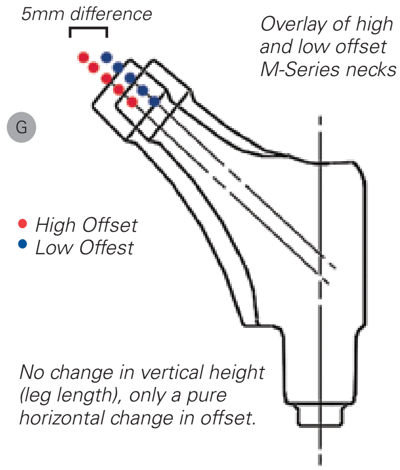

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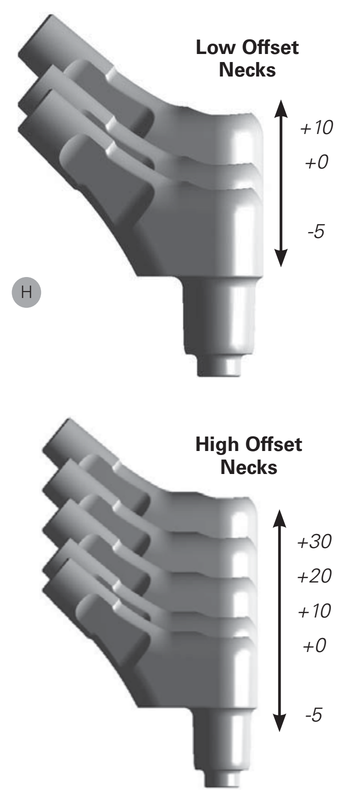

No change in offset, only increase/ decrease in pure vertical height.

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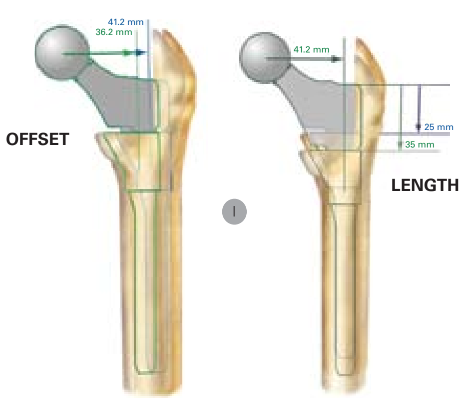

Adjust offset without affecting leg length

Adjust leg length without affecting offset

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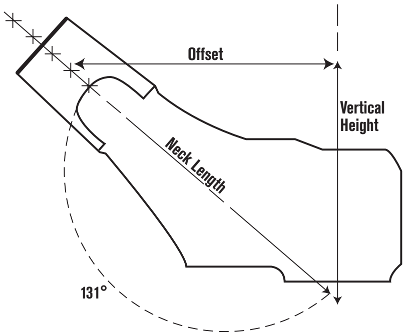

J When changing from a -3.5mm head to a +0mm head, it is important to note that although the neck length increases by 3.5mm, offset and leg length increase by approximately 2mm and 2mm respectively; it is not a 1:1 ratio. In order to get increased offset without affecting leg length (and vice versa), low and high offset neck segments are offered as well as neck segments of varying vertical heights.

M-SERIES OFFSETS* (mm)

Femoral Heads	Low Offset	High Offset
-3.5	34	39
+0	36	41
+3.5	39	44
+7	42	47
+10	44	49

**Values are rounded up to the next whole number.*

RANGE OF MOTION

Dislocation is the most common post-operative complication of total hip arthroplasty today,[7] making range of motion a critical feature in the design of total hip arthroplasties. Prosthetic impingement and range of motion are markedly influenced by the configuration of the head/neck region of the femoral component.[8]

K The M-Series neck cross-section is minimized to increase range of motion, ultimately resulting in less chance of post-operative dislocation.

With a cross sectional diameter of 8mm and a head/neck ratio of 3.5 when using a 28mm head, the M-Series neck segment offers an optimized head/neck ratio and an improved range of motion.[9]

Strength is maintained by increasing the amount of material on the lateral side, where fatigue loads are greater. Material is minimized on the medial aspect of the component, thereby increasing range of motion in both flexion and extension.

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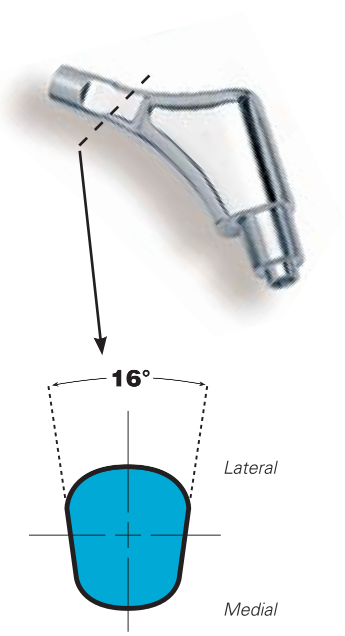


USING A PROXIMALLY LOADED STEM IN TOTAL HIP ARTHROPLASTY

L The M-Series design follows the proximal fixation philosophy. Proximal fixation is well documented in orthopaedic literature as a method for reducing the incidence of proximal stress shielding and bone resorption, which has been linked to eventual loosening of the implant and failure of the hip arthroplasty.[10]

What affects stress-shielding?

1. **Implant design:** How the stem geometry fits into the bone and how it transmits the axial, bending, and torsional loads borne by the proximal femur.
2. **Interface bonding characteristics:** Maximizing stability at the proximal stem/bone interface and how loads are transferred at the interface (fit, coating, ongrowth).

Step 2: Conical Reaming

Once the diaphysis is properly prepared for the distal stem segment, it is necessary to prepare the bone for the metaphyseal segment. This bone preparation is conducted in two steps, beginning with conical reaming.

O Using the color scheme established by the straight reamers, the appropriate pilot is selected and assembled onto the conical reamer. This pilot will center the conical reamer in the previously reamed canal.

Conical reaming is performed sequentially beginning with the 19mm reamer until approximately 1mm of cancellous bone remains in the metaphyseal region of the femur. Markings on the reamer indicate appropriate reaming depth for the calcar replacing metaphyseal segment and the standard metaphyseal segment.

The trailing flutes on the conical reamers are specifically designed to lateralize the reamer in the greater trochanter. Forward reaming should continue when withdrawing the conical reamers from the femoral canal, allowing the reamers to remove enough lateral bone to ensure neutral alignment of the stem and clearance for accurate placement of the definitive metaphyseal segment.

Depth markings

Conical reamer pilot

O

Step 3: Metaphyseal Milling

Through a precise milling process, metaphyseal milling determines the flare size of the definitive implant. To determine the size instrument for milling, refer to the last conical reamer used. Once selected, the appropriately colored pilot is attached to ensure central alignment of the instrument within the femoral canal.

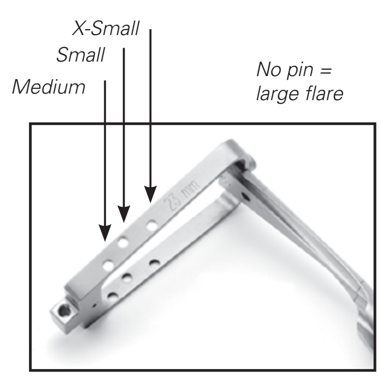
P In order to properly prepare the flare of the metaphyseal segment, the mill guide shaft should be inserted to the level of resection using the scored mark on the mill guide shaft as a depth reference.

Q The mill guide basket has sizing pin holes to prepare the various flare sizes. The pin hole closest to the shaft is for the x-small segment, the next hole is for the small segment and so on.

P

Bone after milling is complete

Q



Step 4:

Free rotational movement between the stem and metaphyseal trials allows the stem trial to be guided into the femur while following the natural bow of the femoral canal. This is especially important when inserting and extracting a curved trial.

Taking note of the orientation of the diaphyseal bow will facilitate definitive implant insertion along the appropriate plane of curvature.

R **Perhaps one of the most significant features of the M-Series trials is the ability to implant the definitive stem and metaphyseal segments and mate them with the trial neck segment. This allows more accurate neck segment positioning and overall joint stability.**

R

M-SERIES TESTING DATA

Independent testing was performed at The Orthopaedic Research Laboratory in Cleveland, Ohio. Published data was used for comparison purposes and included the following.

"Fatigue Behavior of a Titanium Femoral Hip Prosthesis with Proximal Sleeve-Stem Modularity" by J.J. Krygier, A.R. Dujovne and J.D. Bobyn.[11]

"Surface Analysis of the Taper Junctions of Retrieved and In Vitro Tested Modular Prostheses" by J.D. Bobyn, A.R. Dujovne, J.J. Krygier and D.L. Young.[12]

Continuous product improvement is a priority at Exactech. When a new technology was identified that could enhance the fatigue strength of metals, the M-Series was selected as a logical first application.

S Low Plasticity Burnishing (LPB) is a patented process that imparts residual compressive stresses to surfaces of metal parts. These residual compressive stresses in the part surface counteract the tensile stresses applied during loading. Fatigue failure occurs primarily when cracks initiate on the surface of a part due to application of tensile stresses, and then propagate until complete fracture. However, if the surface of the part is in compression, cracks are less likely to initiate. Furthermore, parts treated with LPB have a polished appearance, which reduces the incidence of fretting and surface defects that can lead to crack initiation.

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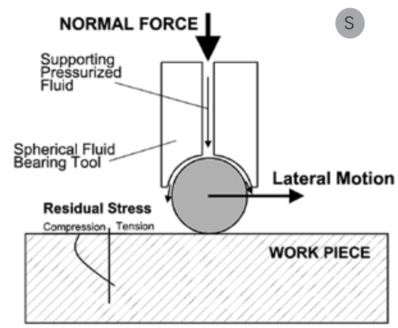
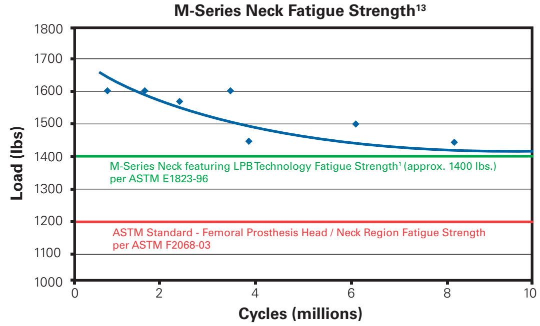


T Fatigue testing was conducted per ISO 7206-6 test method. A fatigue curve was developed and defined an endurance limit of approximately 1400 lbs., or 8.5 times body weight. This result exceeds the ASTM standard for femoral prosthesis head/neck region at 1200 lbs.[13]

T

M-Series Neck Fatigue Strength[13]



3. **Implant materials:** Material elastic modulus controlling the comparative bone-implant stiffness.

In order to properly transmit load so that stress shielding is minimized, the AcuMatch M-Series features the following design characteristics:


L

Distal Stem

Titanium material reduces stiffness to transfer bending loads. Its lower modulus of elasticity (stiffness) as compared to cobalt results in decreased stress shielding.

Flutes transmit torsional load while the polished surface reduces axial load sharing distally, preventing proximal shielding of bone. This allows axial motion at the stem surface resulting in a loadsharing device.

Coronal slot reduces distal stem stiffness to accommodate bending loads, reduce thigh pain, and avoid stress fractures.

Metaphyseal

Titanium plasma coating is biocompatible, allowing osseointegration and metaphyseal fixation. The proximal titanium plasma coating is circumferential, leading to transfer of axial, bending and torsional loads to the proximal bone-implant interface, thereby helping to maintain proximal bone stock.


M

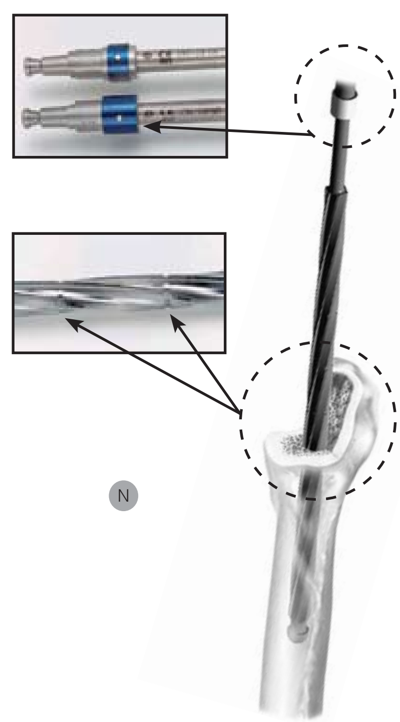
The plasma coating features a "scratch-in" fit to facilitate ongrowth and create physiologic stress transfer. The tapered design transmits axial load proximally and results in an "intimate" tight fit with the proximal bone. Micromotion between implant and host bone is minimized in order to achieve biologic fixation and maintain integrity of the proximal bone.

PUTTING IT ALL TOGETHER… M-SERIES INSTRUMENTATION

Step 1: Straight or Flexible Reaming

M In order to prepare the medullary canal for the distal stem segment, straight or flexible reaming is required. Straight reaming is indicated when using a straight distal stem segment. Flexible reaming is indicated when using a curved distal stem segment. The straight reamers are not endcutting, thereby allowing for lateralization while preventing perforation of the cortex.

N Straight reaming is conducted sequentially until cortical bone is engaged. Markings on the reamer indicate the depth to which the reamer should be advanced according to the stem length selected. Color coded bands indicate reamer diameter and determine the appropriate pilot to select for the conical reamers and the metaphyseal mill guide as well as the color of the appropriate stem trial.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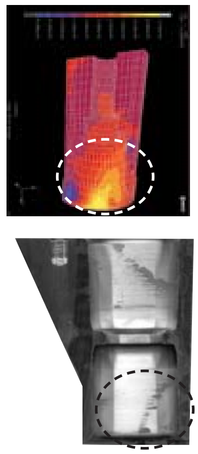
Finite element analysis predicting taper behavior was found to be consistent with actual performance after fatigue testing.



- *Contact pattern shows circumferential taper contact*
- *Contact pattern reflects designed behavior of taper contact*
- *Lack of burnishing marks reflects rotational stability*

LPB is applied to a part by rolling the spherical tool across the entire surface in adjacent passes. On the M-Series, LPB is applied to the distal neck taper creating a compressive stress field on the entire taper surface.

Four stems were analyzed for wear after 10 million cycles of loading in three-point fatigue with torsion in a dry environment. Offset for all samples was 49mm. Two critical factors were analyzed:

1. Percentage of total area of the taper that was effected by wear; and

2. Severity of wear which was classified as follows:
   a. Severity Type A: no or slight wear
   b. Severity Type B: mild wear (burnishing or slight roughening)
   c. Severity Type C: extensive wear (delamination and pitting)

Sectioned samples of the test samples are shown below. Wear test results for the AcuMatch M-Series, as reported by Postak, et al (The Orthopaedic Research Laboratory) were as follows.

Severity of wear and percentage of damage:
With loads exceeding 6.4 times body weight, only 5.9 - 7% of the total taper area exhibited any measurable wear. Of the areas exhibiting wear, only severity type "B"—mild wear (burnishing or slight roughening)—or less was observed.

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13. Data on file at Exactech, Inc.

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