Engineered for long term stability, pain reduction, and optimal fixation for revision cases

The Mallory/Head® modular revision system offers stability at the time of surgery, fixation proximally in a compromised femur, and load transfer from proximal to distal in a physiological manner.

Distal stems are offered straight and bowed, porous coated, and splined.

Porous Plasma Sprayed for Long Term Stability
Biomet’s PPS® Porous Plasma Spray may provide enhanced fixation and is supported by decades of clinical use.1

Designed to Reduce Thigh Pain
The matte-finish distal tip and coronal slot are designed to reduce the possibility of thigh pain and pedestal formation.
Proximal calcar components offer 34mm, 45mm, and 55mm resection levels in five sizes designated from small to large as A, B, C, D, and E.

Patented Roller Hardening Technology
Roller-hardened tapers provide up to three times more strength in cantilever beam testing than standard, non-roller hardened tapers.

Made to Meet the Patient’s Needs
Five available resection levels in five different proximal body sizes simplify the process of matching patients’ anatomies.

Supplied with Canal-Sealing Locking Screw
The locking screw secures the proximal body and distal stem connection while also sealing the implants from errant soft tissues or other potential debris. It also helps to seal the modular junction from the joint space.

Engineered to Preserve Abductor Function
A multitude of claws and bolts are available for adjunct support and fixation of the proximal body, and to aid in the preservation of good trochanteric bone.
In complex revision surgery, distal fixation is often needed as an adjunct to proximal fixation. The Mallory/Head® modular system incorporates two distal stem designs including porous coated and splined stems. Where additional length is required to span distal cortical defects and provide additional fixation in the distal femur, 200mm to 300mm stems are available in coating levels ranking from 40% to 100% of the stem length. Distal stem diameters range from 11mm to 19mm for optimum patient fit. Macro sizes are available with stem diameters up to 23mm and stem lengths of 350mm.

The Mallory/Head® Modular Calcar Revision System also offers an STS™ Splined Tapered Stem. The design of the STS™ stem incorporates a 2° taper with sharp splines to engage the distal cortices. Its modularity with the “load sharing” proximal calcar component makes it a good offering in the modular revision system. The design allows for solid fixation in the distal femur with less voluminous metal. This lower modulus construct could potentially reduce end-of-stem pain often associated with distal fixed components. Stem diameters range from 14mm to 20mm in 1mm increments with stem lengths 200mm and 240mm.
Roller hardening is a specialized, patented manufacturing process used to compress or “work harden” the taper region of the distal stem. This process increases the hardness of the titanium alloy metal at the interface of the taper junction, thus making the construct more resistant to fretting which may lead to fracture. Greater resistance to fretting translates into greater fatigue strength of the modular distal stem. This method of work hardening the taper is a patented process (U.S. patent #6,067,701) developed and owned by Biomet, Inc.

![Graph showing significant increase in taper strength with roller hardened taper. All groups were tested in a cantilever beam testing fixture.](image_url)

As a result, the roller hardening process triples the endurance limit of the taper junction in cantilever beam fatigue testing. This added strength meets the increased demands being placed on the taper junction due to: (A) lack of proximal bone stock; and (B) addition of high demand proximal components (lateralized and/or anteverted).
**Distal Canal Reaming**
Flexible reamers over a guide wire are used to ream distally. Over-reaming is recommended when using a bowed stem.

**Proximal Rasping**
The proximal broach prepares the metaphysis and is used in conjunction with a 170mm straight distal pilot that corresponds to the size of the last flexible reamer used. The broach and distal pilot are locked together with the self-contained screw in the proximal segment. The location for the medial keel is marked at this time. Once the broach is removed, a burr prepares the bone for the keel.

**Trial Implant Insertion**
Utilizing the correct distal trial, a trial proximal head/neck segment is used to confirm proper fit and anteverision. Once confirmed, the trial is locked together with the self-contained screw in the proximal segment. Be certain to position anteriorly the “L” or the “R” etched on the proximal component for the appropriate left or right hip. Position anteriorly the “A” on the distal component. This will lock the trial components in the proper plane.

**Determining Version**
After extracting the trial stem from the femur, place the trial on the sundial upside down. Let the coronal pin on the sundial descend into the coronal slot in the trial and tighten thumbscrew knob.

**Reproducing Version**
Maintain the set version position and place the appropriate sized proximal implant on the sundial. Then, lightly place the appropriate distal implant into the proximal implant’s taper being sure to place the “A” (for anterior) facing the same direction as the “L” for a left hip or the “R” for the right hip. Rotate the distal component to align the coronal slot with the coronal pin. This will reproduce the identical version from the trial. Impact the taper with a head pusher and mallet.
Final Implant Insertion
After components are impacted, insert the segmental locking screw. The modular calcar inserter is then used to seat the implant as a single unit.

Bolt and Claw Preparation
With the final implant in place, the bolt hole may be drilled from medial to lateral or by utilizing the pictured lateral-to-medial drill guide, depending on the surgical approach.

Measuring for Plate or Lateral Claw Connector
A bolt hole gauge is used to determine the length of the final assembly for the plate and claw connector.

Claw Assembly
Insert the oblong bolt medially and hold into place with finger. Determine the claw size, medium or large, and attach to the greater trochanter. The appropriate size lateral claw connector is placed through the claw and tightened into the oblong bolt with a 5.0mm screwdriver.

Bolt Assembly
Insert the oblong bolt medially and hold into place with finger. An optional 3.5mm angled hex bolt holder may also be utilized. A 5.0mm T-handle hex wrench is then used to tighten the plate/bolt assembly.
Surgical Technique

To address complex revision cases, the Mallory/Head® modular instruments provide for ease of insertion as well as profound accuracy. With the ability to independently size the distal and proximal femur, the Mallory/Head® modular system provides customized fixation at the time of surgical intervention for revision arthroplasties.

Preoperative Planning

The femoral component must be stable and have adequate host bone support for predictable success. By utilizing X-rays and implant templates, a plan can be coordinated to ensure that this takes place. The platform area to be fashioned for the proximal calcar replacement can be approximated by utilizing the X-rays with regard to bone loss and bone quality. Final determination frequently cannot be made until the actual time of surgery, however with appropriate planning, a consistent operative plan with alternatives can be formulated. Selection of the proximal resection level can be predicted in order to restore leg length and to adjust the offset.

It is desirable to obtain accurate fit and fill with both the proximal and distal portions of the prosthesis. The length of the stem should be such that the stem of the prosthesis extends at least 2 cm beyond any perforation or lesion. In situations where the proximal portion of the prosthesis is seated on good quality bone, where the keel is keyed into the medial calcar region, and where good prosthesis/calcar contact is present, the bolt may not be necessary. In situations where there is not a complete proximal platform on which to seat the prosthesis or where bone quality or bone contact is incomplete as a result of bone destruction, the trochanteric bolt should be used. Biomechanical studies have demonstrated that this is the last line of defense in regard to proximal stability. It is not necessary to have complete circumferential bone present for calcar support. It is necessary, however, to have good quality bone for calcar support, making certain that at least 50% of the proximal component is supported on good quality host bone.

This brochure demonstrates the surgical technique developed by Thomas H. Mallory M.D. and William C. Head, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the prosthesis in each individual patient. Biomet is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.
Patient Positioning and Surgical Approach

The patient should be placed in a full lateral position with positioning devices placed to ensure complete patient stability (Figure 1). An anterolateral approach through a lateral curvilinear incision is recommended (Figure 2). The incision begins superiorly and posteriorly to the greater trochanter and extends distally along the lateral aspect of the femur, providing sufficient length for reconstruction and cement removal. When major acetabular reconstruction is present, a trochanteric osteotomy may need to be performed.

Removal of a Cemented Component

Care should be exercised when removing a femoral component and proximal cement to prevent a fracture in the trochanteric region or proximal femur. Fractures may be avoided by making certain that the lateral shoulder of the implant is not impinging on or buried into the greater trochanter. Once the implant is removed, the cement in the proximal femur can easily be removed with osteotomes or ultrasonic equipment (Figure 3).

If proximal bone removal is needed in debridement, proceed with the proximal resection for the calcar prosthesis. This allows excellent visibility of the upper femur and canal access for cement removal. Controlled anterior femoral perforations are preferable in the debridement of the distal femur. The most distal perforation is made at the inferior pole of the cement column. X-rays are useful in accessing that position. Cement can then be easily removed with osteotomes or ultrasonic equipment (Figures 4a and 4b).
Removal of an Ingrowth Component

When removing an ingrowth component, an extended trochanteric osteotomy is usually helpful. If ingrowth is present proximally it is beneficial to proceed with the proximal resection for the calcar prosthesis. This allows for proximal loosening of and better access to the implant. In fully coated devices this procedure is almost always necessary.

The fully coated device can then be cut with a carbide bit and a trephine reamer can be placed over the remaining distal portion to remove the femur. It is usually impossible to manually drive out a well-fixed ingrowth stem (Figures 5a–5c).

Evaluation of Bone Quality

The modular calcar replacement prosthesis should have a stable cortical platform fashioned on to the proximal femur. The shoulder of the prosthesis should be in contact with the cancellous bed of the greater trochanter. **Note: It is extremely important to assess the quality of femoral bone and make the platform for the femoral prosthesis as proximal as possible.**

In the majority of revision situations, the platform resides near the lesser trochanter. (At times, it is possible to make the platform and still have bone atrophy or a bony defect.) In these situations, it is first necessary to ensure that the fashioned platform is adequate for seating of the prosthesis. Then, instead of removing unnecessary bone, cortical strut bone grafting is performed to ensure long-term prosthetic stability and support. In such situations, the patient must be kept to limited weight bearing until bone graft healing has occurred. In situations where strong host cortical bone exists, weight bearing as tolerated may begin based on surgeon discretion.
**Determination of Resection Level**

The calcar cutting guide or a trial prosthesis as a guide is used to make the proximal resection (Figures 6a and 6b). The modular calcar proximal component comes in 34, 45, and 55mm resection levels (Figure 7).

It is necessary to have a stable platform on which to place the prosthesis. As stated earlier, in some situations proximal bone grafting must be done. At least two-thirds of the prosthetic platform should be supported by quality host bone.

**Femoral Canal Preparation**

Flexible reamers over a guide wire are utilized for distal reaming when a bowed distal stem is preferred (Figure 8). The distal femoral reaming for the 220 and 250mm should progress to approximately 1mm over the selected implant size to accommodate the bow of the component. Additional over-reaming may be necessary if a distal stem with 80% porous coating is utilized.

Cylindrical canal reamers are applied in preparing the distal femur when utilizing a 170mm straight distal component. Over-reaming is not necessary when implanting the 170mm straight, smooth distal stems (Figure 9a).

Reaming for the STS™ distal stem requires the use of the STS™ reamers. STS™ reamers are advanced into the canal until cortical chatter is obtained. A line-to-line fit is recommended for the STS™ stem. There are four lines on the reamer to identify the various proximal components and STS™ stem lengths (Figure 9b).

1st line (most distal): Represents the 200mm STS™ distal with “A” Mallory/Head® proximal body.

2nd line: Represents the 200mm STS™ distal with a “B, C, D, and E” Mallory/Head® proximal body.
Rasp Insertion and Reduction
Rasping the proximal femur may not be necessary or even possible when dealing with a compromised femur. If the proximal femur is not entirely compromised, a rasp can be utilized.

Rasp Assembly
The 70mm distal pilots are recommended when rasping. The appropriate sized distal pilots are attached to the selected proximal rasp by a self-contained segmental locking screw located in the proximal rasp. The screw is tightened with a 0.5mm screwdriver (Figure 10).

Rasp Insertion
Upon assembly of the rasp, insert it into the femur to contour the proximal envelope. The distal pilots help to assure proper alignment with the shaft axis. Carefully advance the rasp until it becomes snug, then withdraw and repeat until the rasp is in position. The medial keel is then marked with methylene blue where it comes in contact with the medial calcar (Figure 11). After marking, the rasp is removed and a groove or recess is made in this same location, using a power burr. With the rasp reinserted, a trial reduction can be performed utilizing trial heads.

Fig. 10

Fig. 11

Trial Insertion and Reduction
Trial Assembly
The final length distal provisional is attached to the appropriate size trial proximal prosthesis. When trialing with the 220mm, 250mm, and 300mm bowed distal provisionals, an “A” for anterior is marked on the distal tip of the trial stems. An “L” for left and an “R” for right is marked on the opposite sides of the proximal trials. To assemble and trial for a left femur, place the proximal trial segment with the “L” facing up over the appropriate sized bowed distal trial with the “A” facing up. Once the trial is assembled, tighten the self-contained locking screw in the proximal trial with a 0.5mm screwdriver (Figure 12). *Note: When trialing for a right hip the “R” is facing up on the proximal trial.*

Fig. 12

Trial Insertion
In order for the trial to be stable, it must be inserted beginning at 90° of anteversion and gradually turned into neutral or slight anteversion as it progresses in the canal. The trial stem should seat firmly on the horizontal femoral platform with the medial keel in the groove or recess. With the trial in place, a proper reduction can be performed to assess joint stability. If a change in anteversion is required, the locking screw is loosened and the anteversion is adjusted. If the anteversion is adjusted, the recess or groove for the medial keel may need to be enlarged to allow flush seating of the platform (Figure 13). The groove implant stability is an absolute must. Care must be taken to adjust leg length and to evaluate the offset.

Fig. 13
**Optional Version Setting**

**Determining Version**
After extracting the trial stem from the femur, place the trial on the sundial upside down. Let the coronal pin on the sundial descend into the coronal slot in the trial and tighten the thumbscrew knob (Figure 14). A scale on the base of the sundial will indicate the degrees of version of the trial stem.

**Stem and Bolt Insertion**

**Stem Assembly**
Maintain the set version of the sundial and place the appropriate sized proximal implant on the sundial. Like the trial, the proximal implant is marked with an “L” and an “R” and the distal stem is marked with an “A”. After placing the appropriate sized proximal implant on the sundial, lightly place the appropriate distal implant into the proximal implant’s taper, being sure to place the “A” (for anterior) facing the same direction as the “L” for a left hip or the “R” for the right hip. Rotate the distal component to align the coronal slot with the coronal pin. This will reproduce the identical version from the trial (Figures 14 and 15). Impact the taper with a head pusher and mallet and insert the segmental locking screw (Figure 16).

**Stem Insertion**
The implant must be inserted in the same manner as the trial stem. Begin at 90° of anteversion, gradually turning the implant into the correct position as it is driven into place. The turn should be started after the tip of the stem passes the isthmus of the upper femur (Figure 17).
Bolt Hole Preparation

With the implant in place, the need for a trochanteric bolt or claw can be determined. With an anterior-lateral approach, the bolt hole is prepared by using a $\frac{3}{8}$" drill bit from medial to lateral through the greater trochanter (Figure 18). With a posterior approach, the bolt hole can be prepared using the drill guide which allows drilling from lateral to medial (Figure 19). The correct length of the plate or lateral claw connector can be determined by utilizing the bolt depth gauge. The bolt depth gauge is placed medially through the implant and greater trochanter and the correct distance is measured (Figure 20). Note: All the medial bolts are the same lengths to ensure that the union between the plate or lateral claw connector and the bolt are contained within the housing of the calcar prosthesis.
Bolt Assembly
To assemble, the medial bolt is held with finger pressure as the correct length plate is tightened laterally with a 5.0mm T-handle (Figure 21). The medial bolt is oblong in shape to help prevent rotation within the bolt hole (Figure 22). The plate should be screwed down until it is tightened in place (Figure 23). Note: In cases where the trochanter is porotic, care should be taken in tightening.

Claw Assembly
The claw is available in two sizes. Each claw provides multiple positions where the lateral claw connector can be placed to adjust for optimal claw height. To assemble, the medial bolt is held with finger pressure as the correct length lateral claw connector is tightened laterally with a 5.0mm T-handle (Figure 24). The lateral claw connector incorporates five lengths to attach with the medial oblong bolt.

Final Trial Reduction
After insertion of the modular calcar prosthesis, either with or without the optional trochanteric fixation, a final trial reduction is performed. Prosthetic stability, leg length assessment, and femoral offset must be evaluated at this time. Once the correct length head is determined, impact the final femoral head (Figure 25).
Mallory/Head® Modular Calcar Metaphyseal Segments

Modular Head Options

<table>
<thead>
<tr>
<th>Neck Angle 135°</th>
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<tbody>
<tr>
<td>Length to Center of Standard Head</td>
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<tr>
<td>Stem Length</td>
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Each proximal resection level may be coupled with three distal stem options for stem lengths of 170, 220, and 250mm.
# Mallory/Head® Modular Calcar Dimensions & Offsets

## 34mm Femoral Resection Level

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<thead>
<tr>
<th>Size</th>
<th>Neck Angle</th>
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<td>E</td>
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## 55mm Femoral Resection Level

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## Overall Lengths to Center of Standard Head (28mm)

<table>
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<tr>
<th>Resection Level</th>
<th>Stem Length (mm)</th>
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<tr>
<td>34mm</td>
<td>170 220 250</td>
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<tr>
<td>45mm</td>
<td>208 258 288</td>
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<tr>
<td>55mm</td>
<td>229 279 309</td>
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</table>
Biomet manufactures a variety of hip joint replacement prostheses. Hip joint replacement components include: femoral stems, femoral heads, acetabular shells, and acetabular liners. Components are available in a variety of designs and size ranges intended for both primary and revision applications. Speciality components are available including: acetabular screws, centering sleeves, and canal plugs.

**Materials**

- Femoral Stems: CoCrMo Alloy or Titanium Alloy
- Femoral Heads: CoCrMo Alloy
- Acetabular Shells: Titanium Alloy
- Acetabular Liners: Ultra-High Molecular Weight Polyethylene (UHMWPE)
- Acetabular Screws: Titanium Alloy
- Centering Sleeves: Polyethylmethacrylate (PMMA)
- Canal Plugs: UHMWPE
- Porous Coating: Titanium Alloy

**INDICATIONS**

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatment or devices have failed.

**CONTRAINDICATIONS**

- Relative contraindications include: uncooperative patient or patient with neuromuscular disease.
- Absolute contraindications include: infection, sepsis, and osteomyelitis.

**WARNINGS**

Improper selection, placement, positioning, alignment, and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preoclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture, and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

**PRECAUTIONS**

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear, and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

Biomet® joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal, healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma, and weight gain have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

**POSSIBLE ADVERSE EFFECTS**

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discolouration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.

2. Early or late postoperative infection and allergic reaction.

3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.

Biomet Orthopedics, Inc.                 0-50-096
P.O. Box 587                           Date: 09/05
56 East Bell Drive                  Warsaw, Indiana 46581 USA
4. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and excessive activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.

STERILITY
Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-1683.

Authorized Representative: Biomet, U.K., Ltd.
Waterton Industrial Estates,
Bridgend, South Wales
CF31 3XA U.K.

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet at the contact information provided herein.

References
2. Data on file at Biomet.

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