

MALLORY-HEAD
HIP · PROGRAM™
POROUS PRIMARY SYSTEM

SURGICAL TECHNIQUE

BIOMET®
ORTHOPEDICS

The Mallory-Head® System was designed and developed in conjunction with Thomas Mallory, M.D. and William Head, M.D.

This Mallory-Head® Surgical Technique is utilized by Adolph Lombardi, M.D. and Roger Emerson, 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.

Special thanks to Rod Davey, M.D. for his contributions toward the design of the Lateralized Mallory-Head® Femoral component.

THE MALLORY-HEAD® POROUS PRIMARY SYSTEM

SURGICAL TECHNIQUE

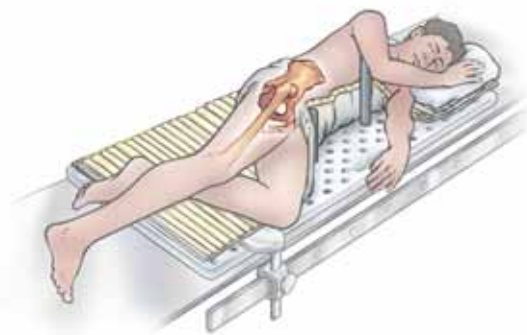


Fig. 1



Fig. 2

PATIENT POSITIONING AND SURGICAL APPROACH

The goal of the surgical approach is to establish adequate visualization of the anatomy so that the entire surgical area is exposed.

The patient should be placed in a full lateral position with positioning devices to ensure complete patient stability. An anterolateral approach via a lateral curvilinear incision is recommended (Figs. 1 & 2).



Fig. 3

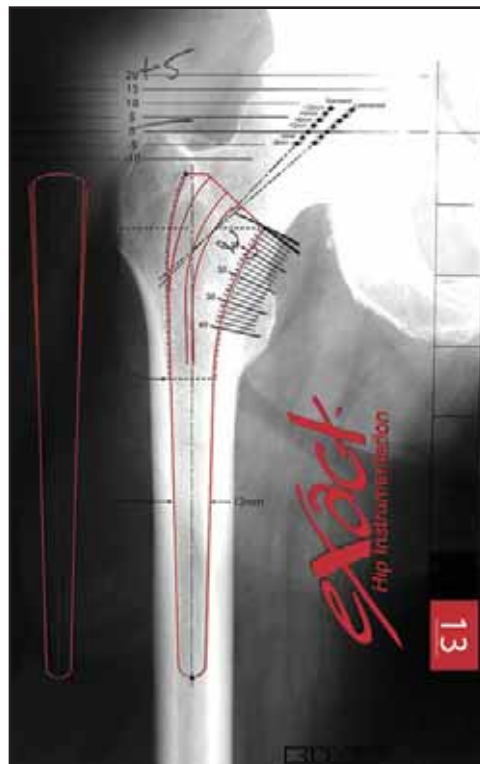


Fig. 4

FEMORAL NECK RESECTION

The Exact™ Mallory-Head® femoral resection guide may be used to mark the femoral neck resection level for an accurate cut (Fig. 3). It utilizes key reference points off of the lesser and greater trochanters that correspond to the measurements on the Exact™ reamers and X-ray templates (Fig. 4). For example, when templating the X-rays, note the measurements on the vertical and medial scales that line up with the greater and lesser trochanters. Place the resection guide on the femur, lining up the vertical scale with the greater trochanter. If utilizing the greater trochanter stop, pre-set it to the closest mark noted during templating. With the trochanter stop resting on the greater trochanter, the medial markings should agree with your preoperative planning. For example, if you measured +7mm on the template, then place the trochanteric stop at the +5mm mark, erring on the side of preserving more bone. Once the appropriate level of resection has been determined, proceed with cutting the femoral neck to allow for re-creation of the appropriate femoral neck length and offset.



Fig. 5



Fig. 6



Fig. 7

ACCESSING THE FEMORAL CANAL

The Exact™ offset chisel is used to access the lateral section of the proximal femoral shaft to clear a channel to accept the tapered reamers without interference from dense bone surrounding the trochanter. The design assures adequate visualization to get lateral enough in the greater trochanter to avoid varus positioning (Fig. 5). A starter reamer on a T-handle may be used to initiate the opening into the distal femoral canal (Fig. 6).

REAMING THE FEMORAL CANAL

The Exact™ Mallory-Head® reamers are proportionally sized reamers with blunt tips that are used to progressively enlarge the intramedullary canal to the size estimated by the preoperative templating. **Note: The Exact™ Mallory-Head® reamers account for the cylindrical distal geometry of the implants (sizes 6mm through 10mm only), thus eliminating the need for a two-step reaming process as was done with the original Mallory-Head® instruments.** Begin with a canal reamer that is 3–4mm smaller than the templated femoral component (Fig. 7). Sequentially ream the femoral canal until cortical contact is made, utilizing the reference bands on the shaft of the reamers to achieve the preoperatively determined depth that corresponds to the markings on the Exact™ templates. The reference markings on the reamers are in 5mm increments. For example, if the templated vertical scale is at +7mm, the greater trochanter stop was placed at the +5mm, then the reamer is advanced so that the depth measurements line up to the greater trochanter at the +7mm mark. If using the medial resection level as a general guide, bury the reamer until the end of the gold nitrided area is at the level of the medial resection. Cortical chatter will be encountered when the appropriate reamer size is reached (Fig. 8).



Fig. 8

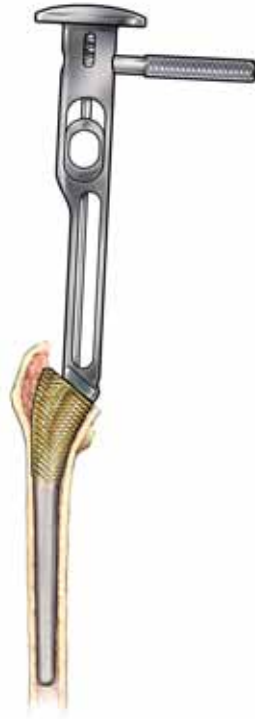


Fig. 9



Fig. 10

CONTOURING THE STEM ENVELOPE

After completing the reaming process, a broach is used to contour the proximal stem envelope. Attach the broach handle to the broach by pulling back on the trigger handle and locking it into place. Begin the broaching process with a broach at least two sizes smaller than the largest reamer used. In order to enlarge the proximal femur, gradually advance the broach in the mediolateral plane, matching the patient's version, until it meets resistance. Repeat the sequence until the templated implant size is reached or until the broach engages the medial cortex and cannot be placed deeper (Fig. 9).

The modularity of the broaches allows for rapid sequential broaching and the ability to accurately trial directly off of the broaches using the magnetic neck trunions.

PLANING THE FEMUR

With the final broach fully seated, remove the broach handle. Place the retractable calcar planar fully over the short post of the broach and machine the femoral neck for optimal implant contact. The calcar planar is specially designed to reach the short broach post and prevent metal-to-metal wear of the post (Fig. 10).



Fig. 11



Fig. 12



Fig. 13

TRIAL REDUCTION

Place the Exact™ magnetic neck trunion trial, standard or lateral, onto the broach post. These trunions are color coded to represent offset. The gold trunion indicates standard offset, while the black trunion represents the lateralized offset. The Exact™ magnetic neck trials are sized to correspond to the final broach and are clearly marked on the top of the trunion (Fig. 11). Select the trial femoral head of desired diameter and neck length. Reduce the hip and evaluate the joint for soft tissue tension, anterior and posterior stability and stability in the sleep position. Any additional adjustments to neck length and/or offset can be completed at this time (Fig. 12).

Mallory-Head® provisional stems are also available for a second trial reduction or as an alternative option to the broach/trunion trial reduction.

Note: Utilizing the broach as a trial does not account for the A/P fins or the porous coating on the implant. These trial stems will aid in preparing the proximal femoral envelope to accept the final implant. The provisional trial stems, gold for standard offset and blue for lateralized offset, match the finned geometry of the final implant exactly, minus the porous coating (Fig. 13).



Fig. 14



Fig. 15

STEM INSERTION

Once the trial reduction is considered stable, remove the broach or trial stem from the femoral canal and attach the implant to the threaded femoral inserter (Fig. 14). The femoral insertion handle assists in controlling rotation of the implant and enables the implant to be inserted into the femoral envelope with the proper amount of anteversion. Care should be taken to match the final anatomic anteversion, which was determined from the broaching step. The Mallory-Head® femoral component's unique fin design can provide for some adjustment in the version of the component if desired by the surgeon. The stem should slide distally into the canal without much resistance until the anterior and posterior fins engage the walls of the prepared canal. Gently tap to steadily seat the prosthesis. If the stem cannot be inserted to the desired position to equalize leg lengths, additional reaming and broaching should be done to seat the implant at the desired level. The surgeon should not impact the prosthesis with excessive force to avoid fracture of the femur. Remove the inserter when the implant is fully seated. A trial head component can be placed on the femoral implant neck trunion for an additional trial reduction, or the selected modular femoral head can be firmly impacted onto the clean dry taper (Fig. 15).

Note: For some femurs with a high valgus angle, difficulty may be encountered seating the implant correctly in the medial portion of the femur. In order to achieve greater distal contact of the implant/femur interface, mill the medial calcar with the appropriate size reamer to widen the calcar. This will enable the implant to seat lower in the femur, providing increased distal contact.

THE MALLORY-HEAD® POROUS PRIMARY SYSTEM

ORDERING INFORMATION

MALLORY-HEAD® FEMORAL COMPONENT

Stem Size	Implant Standard	Implant Lateralized	Stem Length	Broach	Trial Standard	Trial Lateralized	Reamer Tapered
6mm	11-104106		135mm	31-104506	104360		104556
7mm	11-104107		140mm	31-104507	104361		104557
8mm	11-104108	11-104208	145mm	31-104508	104362	104379	104558
9mm	11-104109	11-104209	150mm	31-104509	104363	104380	104559
10mm	11-104110	11-104210	155mm	31-104510	104364	104381	104560
11mm	11-104111	11-104211	160mm	31-104511	104365	104382	104561
12mm	11-104112	11-104212	165mm	31-104512	104366	104383	104562
13mm	11-104113	11-104213	170mm	31-104513	104367	104384	104563
14mm	11-104114	11-104214	175mm	31-104514	104368	104385	104564
15mm	11-104115	11-104215	180mm	31-104515	104369	104386	104565
16mm	11-104116	11-104216	180mm	31-104516	104370	104387	104566
17mm	11-104117	11-104217	180mm	31-104517	104371	104388	104567
18mm	11-104118		180mm	31-104518	104372		104568
19mm	11-104119		180mm	31-104519	104373		104569

Neck Angle Standard 136.5, Neck Angle Lateralized 131.5

MAGNETIC NECK TRUNIONS

Standard (Gold)		Lateralized (Black)	
Sizes	Part No.	Sizes	Part No.
6–10mm	31-104522	8–10mm	31-104526
11–14mm	31-104523	11–14mm	31-104527
15–19mm	31-104524	15–19mm	31-104528



Exact™ Mallory-Head® Template

104097

Exact™ Instrument Cases:

Exact™ General Case I

595100

Exact™ General Case II

595101

Mallory-Head® Specific Cases:

Exact™ Mallory-Head® Reamers

595102

Exact™ Mallory-Head® Provisionals

595094

Exact™ Mallory-Head® Broaches

595103

Biomet® Hip Joint Replacement Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION

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. Specialty 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	Polymethylmethacrylate (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.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

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 preclosure 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.

1. Use Biomet® femoral and modular head component with appropriate matching "Type I Taper", "Type II Taper", or "12/14 Taper".
2. Firmly seat modular head components to prevent dissociation. Thoroughly clean and dry taper prior to attachment of the modular head component to avoid crevice corrosion and improper seating.
3. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
4. Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
5. Perforation entirely through the pelvic bone with dome fixation screws or rim screws is to be completely avoided. Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long can cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
6. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
7. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
8. Acetabular shells should only be used with compatible FDA cleared acetabular liners.

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.

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.

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 discoloration 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. Further, there has been a report regarding an association between articulating surfaces of: 1) CoCrMo alloy on CoCrMo alloy, 2) CoCrMo alloy on polyethylene, and 3) Titanium alloy on polyethylene in hip replacements and increased genotoxicity. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from hip replacement.
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.
4. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, or excessive activity.
5. Periarticular calcification or ossification, with or without impeding 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.
14. Postoperative bone fracture and pain.

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:

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CF31 3XA U.K.

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For general risk information on hip products, please see Biomet's website.

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Driven By Engineering

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