ECHO® Femoral Hip System

Hip Fracture Surgical Technique

Endo II Uni-polar Acetabular Component

RingLoc® Bi-polar Acetabular Component

BIOMET®

One Surgeon. One Patient.®

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

ECHO® Femoral Hip System

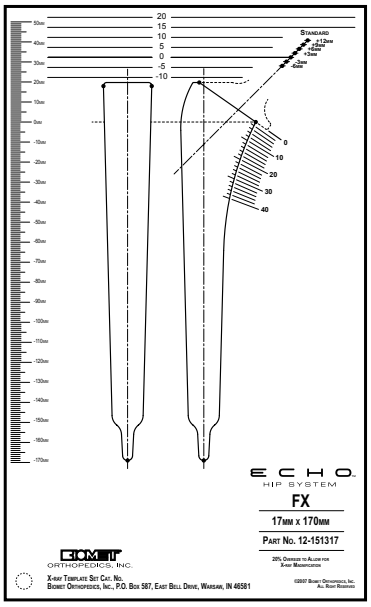


Figure 1

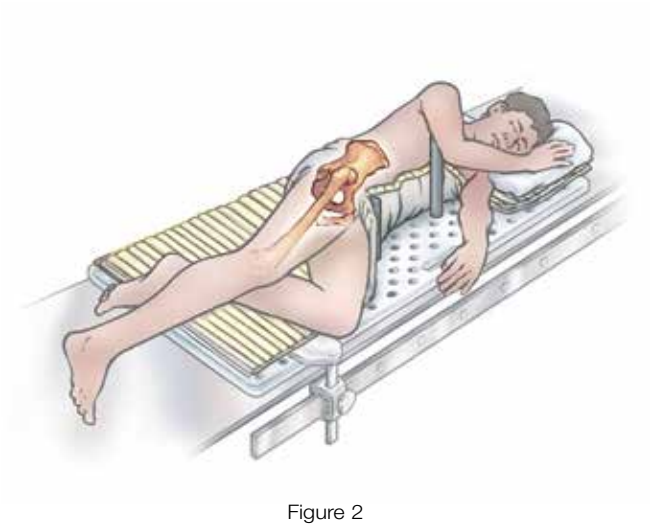


Figure 2

Biomet's Echo® Hip System Offers Three Stem Variations

Echo® FX Stem: Forged cobalt alloy cemented or press-fit stem

Echo® PF Stem: Forged titanium alloy grit blasted press-fit stem

Echo® Bi-Metric® Stem: PPS® forged titanium alloy press-fit stem

Any one of the Echo® Hip System components may be utilized in total or hemi hip arthroplasty.

Preoperative Planning

Preoperative templates are provided for determining optimal component size, femoral neck resection level and appropriate neck length (Figure 1). Radiographs should include a full A/P (anteroposterior) view of the pelvis including the proximal one-half of both femurs and a lateral view of the proximal half of the affected femur.

Surgical Approach

The Echo® Hip System is designed to accommodate any standard approach based on the surgeon's experience or personal preference. Adequate exposure that allows bony landmark visualization, component alignment and thorough soft tissue assessment can contribute to more successful results (Figure 2).

The Echo® Hip System was designed and developed in conjunction with Michael Berend, M.D.; Christian Christensen, M.D.; Philip Faris, M.D.; Kevin Garvin, M.D.; Douglas Jessup, M.D.; Michael Keating, M.D.; John Meding, M.D. and Jeffery Mokris, M.D.

This hip facture surgical technique is utilized by Kevin Garvin, M.D. Biomet as the manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.

Figure 3

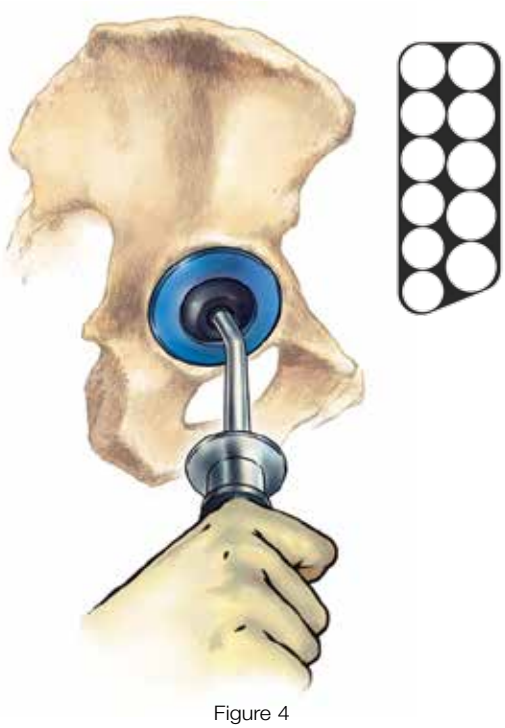


Figure 4

Resecting the Femoral Head

A broach/provisional or the femoral resection template may be used as a template for the femoral resection level (Figure 3). If fractured, remove the head/neck fragment with a corkscrew.

Gauge Acetabulum

Sizing of the acetabulum is conducted by using provisional shells that are attached to the gauge handle (Figure 4). These provisionals are utilized for both bi-polar and uni-polar applications. You may also utilize the femoral head gauge to determine the diameter of the resected femoral head.

Note: Please refer to the product listing for femoral head trial size options.

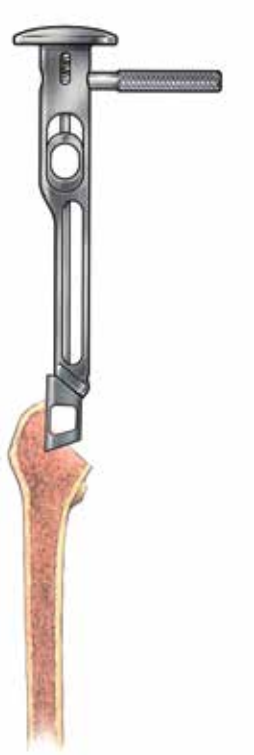


Figure 5

Figure 6

Opening Femoral Canal

A hollow chisel or starter reamer can be used to open the femoral canal (Figures 5 and 6).

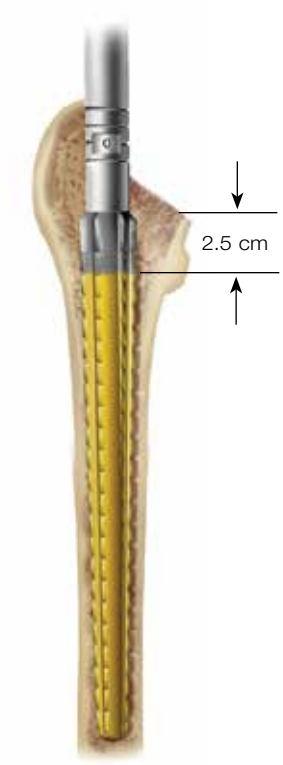


Figure 7

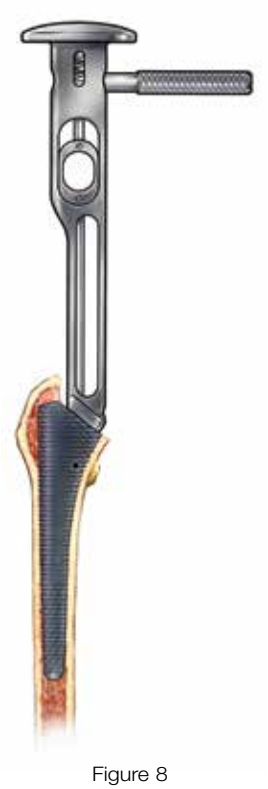


Figure 8

Reaming the Distal Femur

Note: Fully toothed broaches are recommended with the Echo fracture system. If using fully toothed broaches, the reaming step may be skipped. Partially toothed broaches can be used, but care should be taken when reaming to ensure the reamer is advanced 2.5 cm (approximately 1 inch) past the medial resection level of the femur, relative to the level of gold nitride coating (Figure 7).

Tapered side cutting reamers are introduced in a sequential fashion beginning with the smallest size reamer and progressing until the cutting flutes encounter resistance from the endosteal wall. The reamer is advanced until the gold portion is beyond the level of the planned medial resection (Figure 7).

Broaching the Proximal Femur

Begin broaching with the fully toothed broach that is at least 2 mm smaller than the last reamer size used. It is important that the broach is oriented so that the medial/lateral axis of the broach is parallel with the anatomic medial/lateral axis of the femoral neck. A sequentially larger broach is used until ideal or templated size is reached.

Example: Ream 12 mm, sequentially broach to 12 mm (Figure 8).

Note: The black Exact™ Alliance® RPP broaches must be used in Echo® FX and PF fracture applications.

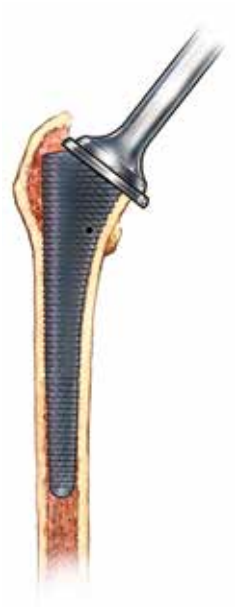


Figure 9

Figure 10

Planing the Calcar

With the broach/provisional properly seated, the calcar is planed flush by using the Exact™ calcar planer (Figure 9).

Note: Fully seat the spring loaded plunger over the broach post prior to powering-up and advancing the body and blade of the planer.

Trunnion Selection

To perform the trial reduction with the indwelling broach, attach the Exact™ Echo® neck trunnion onto the broach post. The neck trunnion for the Echo® PF stem is offered in standard (S) offset only. The neck trunnions for the Echo® Bi-Metric® and Echo® FX stems are offered in standard (S) and lateralized (L) offset. These trunnions are color coded to represent offset. The gold trunnions represent standard offset while the black represents lateralized offset. The Exact™ trunnions are sized to correspond to the final implant. The stem size is clearly marked on the top of the trunnion (Figure 10).

Figure 11

Figure 12

For Endo II

With the appropriate neck trunnion in place, select the desired Endo II trial head and provisional shell components. Biomet offers five neck length options (-6, -3, Standard, +3, and +6 mm) for use with the Endo II uni-polar system. Assemble as shown (Figure 11).

Note: The Endo II trial head will snap into the apical hole of the desired provisional shell component. A trial reduction is carried out to ensure that proper leg length and joint stability have been achieved.

For RingLoc® Bi-polar

With the appropriate neck trunnion in place, select the appropriate RingLoc® bi-polar trial head and provisional shell components. Biomet offers seven neck length options (-6, -3, Standard, +3, +6, +9 and +12 mm) for use with the RingLoc® bi-polar system. Assemble as shown (Figure 11).

Note: Align the circumferential flat on the RingLoc® bi-polar trial head with the desired provisional shell component. The bi-polar head will articulate within the provisional shell component. A trial reduction is carried out to ensure that proper leg length and joint stability have been achieved.

Echo® Cementless Stem Insertion

Select either the Echo® PF, Echo® FX or the Echo® Bi-Metric® implant that corresponds to the last size reamer and broach used.

Example: Ream and broach to a 12 mm. Implant a size 12 mm Echo® PF or Bi-Metric® stem. Attach implant to the inserter tool and impact until the stem stops advancing. Do not attempt to seat the stem further if it fails to advance (Figure 12).

Figure 13

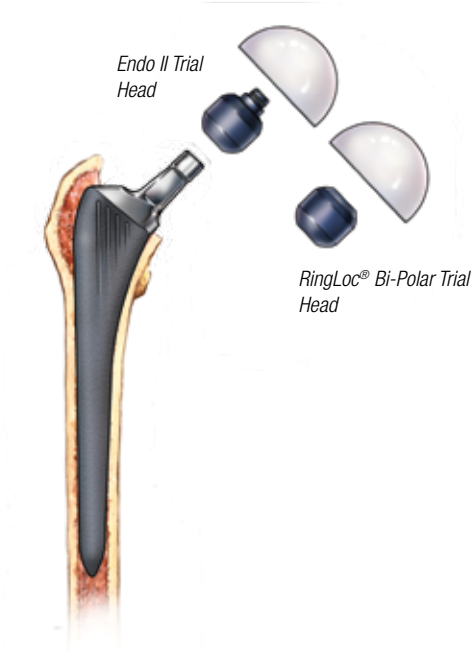


Figure 14

Echo® FX Cemented Stem Insertion

Select the Echo® FX stem that is a minimum of 2 mm smaller than the final reamer and Exact™ Alliance® RPP broach used. Undersizing the component 2 mm will provide for a 2 mm cement mantle (1 mm per side). Undersizing by 4 mm will provide a 4 mm mantle (2 mm per side).

Example: Ream and broach to 12 mm. Select a size 9 mm Echo® Hip Fracture stem to provide a 1.5 mm mantle per side. A distal cement restrictor is placed in the canal to allow a 2cm cement column below the tip of the stem. Cobalt™ cement is injected into the canal in a retrograde fashion and pressurized. Slide the appropriately sized distal centralizer onto stem.

Example: Echo® FX stems accept any size distal tip centralizer and may be matched to prepared canal size. The stem is inserted to a fully seated position, and extraneous cement is removed. Once cement hardening is achieved, a final trial reduction may be done (Figure 13).

Final Trial Reduction

With the implant in place, a second/final trial reduction may be performed utilizing Endo II or bi-polar trial heads. Select the appropriate trial components and assemble as shown in Figure 14.

Endo II Uni-polar *In Vivo* Assembly

Figure 15

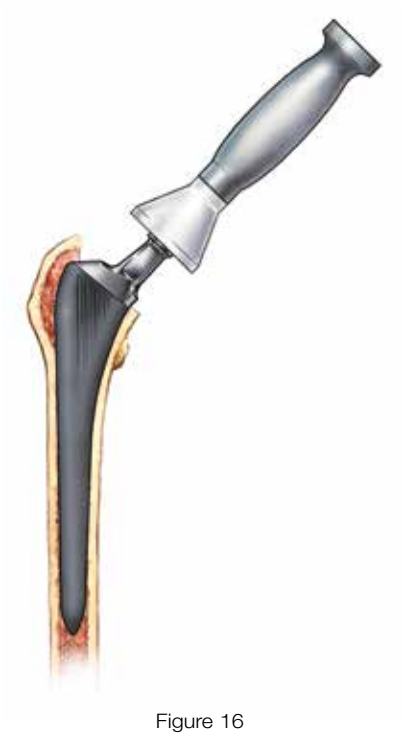


Figure 16

Seating the Taper on the Stem

After determining the desired neck length, dry the femoral component neck trunnion and select the appropriate Endo II taper insert (Figure 15). Seat the appropriate insert with a head driver.

Note: The taper insert may be used on any Biomet® type 1 taper femoral component when implanting an Endo II uni-polar head.

Seating the Head on the Taper Adaptor

Select the desired Endo II uni-polar head and secure it onto the taper insert with a twisting motion. Impact the Endo II head with a head driver (Figure 16).

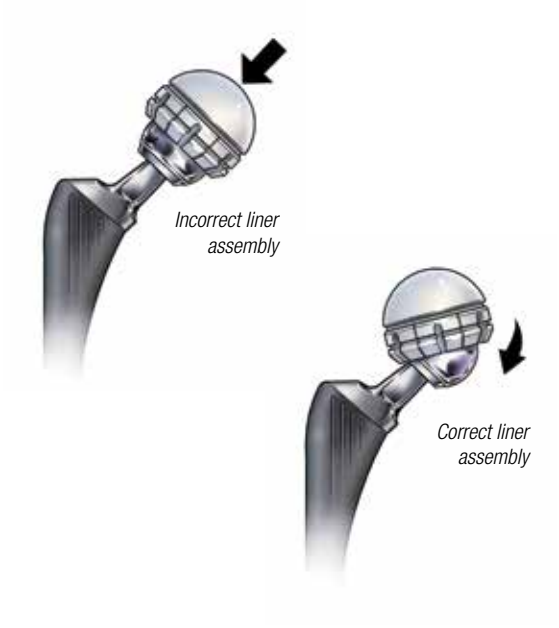
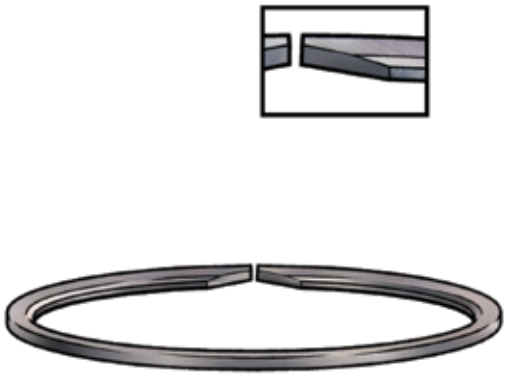


Figure 17



The chamfer on the metal ring must face the opening of the shell.

Figure 18

Impacting the Femoral Head

Select the appropriate 28 mm femoral head that corresponds to the neck length determined at final trial reduction and impact with the head driver.

Assembling the Polyethylene Liner

Lever the polyethylene liner from superior to inferior onto the assembled femoral head until a “click” is heard (Figure 17).

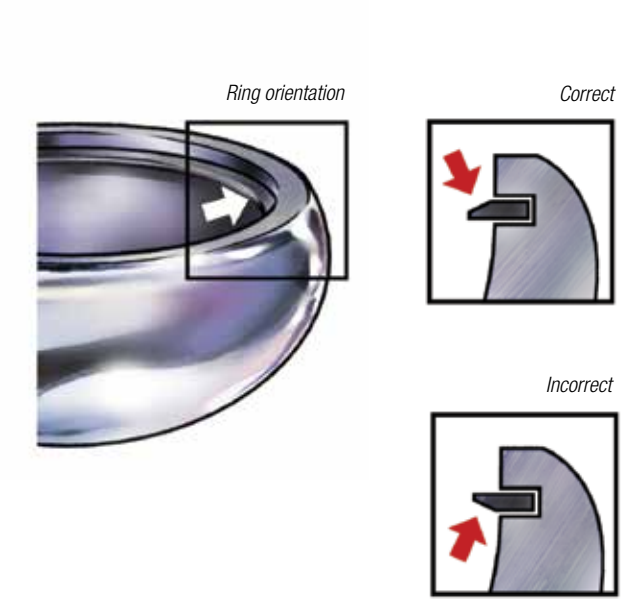


Figure 19

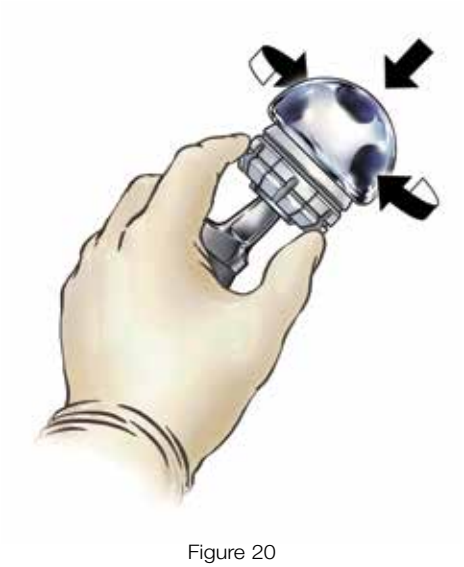


Figure 20

Positioning the Metal Ring

Each shell is packaged with the metal ring in position. Before assembling the metal shell on the polyethylene liner, ensure the metal ring is intact and moves in a circular motion within the groove of the metal shell. Make sure that the chamfer on the metal ring is facing toward the opening of the metal shell (Figure 18) and is visible when looking into the shell (Figure 19).

Assembling the Metal Shell

Hold the liner steady against the femoral head. Twist and push the metal shell onto the liner. The metal shell will be fully seated when the metal ring engages the locking groove of the polyethylene liner (Figure 20).

RingLoc® Bi-polar Back Table Assembly

Figure 21

Figure 22

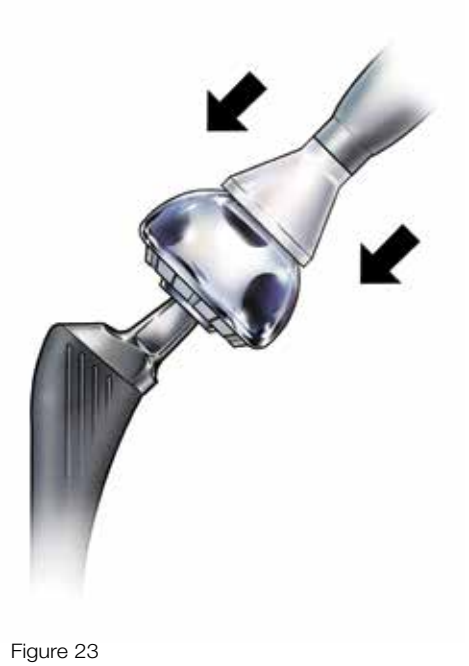


Figure 23

Assembling the Polyethylene Liner onto the Femoral Head

Place the correct femoral head on a sterile field. Using even pressure, apply the polyethylene liner over the femoral head until a click is heard (Figure 21).

Assembling the Metal Shell

While holding the liner steady, twist and push the shell onto the liner (Figure 22).

Assembling the Metal Shell onto the Femoral Stem

Impact the bi-polar onto the inserted femoral component as a unit with several taps (Figure 23).

Disassembly of RingLoc® Bi-polar

Figure 24

Figure 25

Engagement of Liner Removal Tool

There are eight removal tools which are marked with the corresponding cup sizes that they will remove. Choose the correct size tool that matches the cup/liner size to be disassembled (Figure 24).

Position the appropriately sized removal tool over the taper and push it into the slots located on the periphery of the liner (Figure 24).

Insert the removal tool into the polyethylene liner until it is fully flush with the face of the liner.

Removal of Metal Shell

Hold the removal tool against the liner (do not allow the tool to rotate). Twist and pull the metal shell away from the liner. The tool must remain flush with the liner while the shell is being removed (Figure 25).

Removal of Liner

Disengage the removal tool and lever the polyethylene liner away from the femoral head.

Note: If the liner and shell have been assembled without the head, use the bi-polar liner removal dumbbell (31-165341), in place of the stem and head, to pull on for separation.

Disassembly of the Endo II Uni-polar Taper Insert and Shell

Figure 26

Figure 27

Figure 28

Removal of Liner (cont.)

Place the assembled Endo II uni-polar head and taper insert over the separator. Resistance will be felt due to the tines that extend proximally on the separator. **Warning: Do not attempt this if the plunger is assembled to the separator.**

Using hand pressure only, push the head downward until an audible “click” is heard. The taper insert should sit flush on the base of the separator (Figure 27).

Lower the separator onto the plunger while lining the plunger post up with the hole on the bottom of the separator (Figure 28).

Note: The base of the separator will stand several millimeters proud because the taper is still set.

Figure 29

Figure 30

Figure 31

Removal of Liner (cont.)

Carefully place the dome over the Endo II head, plunger and separator (Figure 29).

Using a mallet, impact the plate on the top of the dome. This will enable the tines that have been pushed through the Endo II taper insert to force the taper with the Endo II head to break (Figure 30).

Remove the dome. Remove the head from the taper insert (Figure 31).

Note: Reuse of the head is not recommended.

Remove the separator and the taper insert from the post on the plunger.

Note: Reuse of the taper insert is not recommended.

Using Kocher forceps, squeeze the tines on the end of the separator together and slide the tapered insert off.

Echo® FX Cobalt Chromium Femoral Components

Product	Part Number	Description	Size
	**12-151307** **12-151309** **12-151311** **12-151313** **12-151315** **12-151317**	Echo® FX Femoral Stem - Standard Offset	7 mm 9 mm 11 mm 13 mm 15 mm 17 mm
	**12-151409** **12-151411** **12-151413** **12-151415** **12-151417**	Echo® FX Femoral Stem - Lateralized Offset	9 mm 11 mm 13 mm 15 mm 17 mm

Echo® PF Press-fit Titanium Femoral Components

Product	Part Number	Description	Size
	**12-150307** **12-150308** **12-150309** **12-150310** **12-150311** **12-150312** **12-150313** **12-150314** **12-150315** **12-150316** **12-150317**	Echo® PF Press-fit Femoral Stem - Standard Offset	7 mm 8 mm 9 mm 10 mm 11 mm 12 mm 13 mm 14 mm 15 mm 16 mm 17 mm

ECHO® Femoral Hip System

Instruments

PMMA Distal Stem Positioner

Product	Part Number	Description	Size
	**162656** **162640** **162657** **162641** **162658** **162642** **162659** **162643** **162660** **162644** **162661** **162646**	Centralizer Distal Positioner	9 mm 10 mm 11 mm 12 mm 13 mm 14 mm 15 mm 16 mm 17 mm 18 mm 19 mm 20 mm

Product	Part Number	Description	Size
—	**595609**	Metal Outer (2 Required)	4.5 inch

Tray 1

Product	Part Number	Description	Size
—	**595602**	Plastic Tray One with Lid	—
	**X31-400027** **X31-400028** **X31-400029** **X31-400030** **X31-400031** **X31-400032** **X31-400033** **X31-400034** **X31-400035** **X31-400036** **X31-400037**	Exact™ Alliance® Reamer	7 mm 8 mm 9 mm 10 mm 11 mm 12 mm 13 mm 14 mm 15 mm 16 mm 17 mm

Instruments (cont.)

Tray 2

Product	Part Number	Description	Size
—	**595603**	Plastic Tray Two with Lid	—
	**428195**	R/B Starter Reamer Tapered	—
	**31-112102**	Impact Initial Canal Probe	—
	**31-473192**	Troch Reamer	—
	**31-473190**	Troch Router	—
	**31-555583**	Lateralizing Rasp Reamer	—
	**X31-400001**	Stem Removal Tool Adapter	—
	**X31-400061**	Slap Hammer	—
	**31-473620**	Reamer T-Handle	—
	**31-473191**	Reamer T-Handle Threaded	—
	**31-555605**	Cork Screw Attachment for T-Handle	—
	**31-555617**	Cork Screw Attachment for Cinch Handle (31-55611)	—

ECHO® Femoral Hip System

Instruments

Tray 2 (cont.)

Product	Part Number	Description	Size
	31-400000	Bio-Plug™ Bone Plug Inserter	—
	31-400100	I-M Plug Bone Plug Inserter	—
	**31-555610**	Exact™ Slotted Stem Inserter	—
	**31-555612**	Cinch Femoral Inserter with Fork	—
	**31-555613**	Cinch Femoral Inserter Bullet Tip	—
	**31-555614**	Cinch Femoral Inserter Slotted Bullet Tip	—
	**31-555616**	Cinch Femoral Inserter Slotted / Threaded	—

Tray 3

Product	Part Number	Description	Size
—	**595604**	Plastic Tray Three with Lid	—
	**X31-400003**	Resection Guide Alliance®	—
	**31-555598**	Resection Guide MIH Alliance®	—
	**31-555588**	Hollow Chisel Attachment for Broach Handle	—
	**31-400107** **31-400108** **31-400109** **31-400110** **31-400111** **31-400112** **31-400113** **31-400114** **31-400115** **31-400116** **31-400117**	Exact™ Alliance® RPP Broach Full	7 mm 8 mm 9 mm 10 mm 11 mm 12 mm 13 mm 14 mm 15 mm 16 mm 17 mm

Tray 3 (cont.)

Product	Part Number	Description	Size
	**31-400307** **31-400308** **31-400309** **31-400310** **31-400311** **31-400312** **31-400313** **31-400314** **31-400315** **31-400316** **31-400317**	Exact™ Alliance® RPP Broach Partial	7 mm 8 mm 9 mm 10 mm 11 mm 12 mm 13 mm 14 mm 15 mm 16 mm 17 mm
	**31-555500**	Exact™ Broach Handle	—
	**31-555501**	Exact™ Anterior Supine Broach Handle	—
	**31-473794**	Exact™ Modular Calcar Planer	42 mm
	**406661** **406662** **406663**	Exact™ Blades	38 mm 42 mm 46 mm
	**31-473795** **31-473796** **31-473797**	Exact™ Rasp Style Blade	38 mm 42 mm 46 mm
	**31-162401** **31-162402** **31-162403**	Standard Offset RPP Profile NC Trunnion Trial	7–10 mm 11–14 mm 15–21 mm
	**31-162413** **31-162414** **31-162415**	Standard Offset RPP Profile C Trunnion Trial	7–10 mm 11–14 mm 15–21 mm
	**31-162416** **31-162417** **31-162418**	Echo® FX Lateralized Collared Trunnion	9 mm 11–13 mm 15–17 mm

ECHO® Femoral Hip System

Instruments

Tray 4

Product	Part Number	Description	Size
—	**595605**	Plastic Tray with Lid	—
	**31-401141** **31-401142** **31-401143** **31-401144** **31-401145** **31-401146** **31-401147** **31-401148** **31-401149** **31-401150** **31-401151** **31-401152** **31-401153** **31-401154** **31-401156** **31-401158** **31-401160**	Endo/Bi-polar Trial Head	41 mm 42 mm 43 mm 44 mm 45 mm 46 mm 47 mm 48 mm 49 mm 50 mm 51 mm 52 mm 53 mm 54 mm 56 mm 58 mm 60 mm
	**31-401166**	Femoral Head Sizing Gauges	—
	**31-401135** **31-401134** **31-401133** **31-401132** **31-401131** **31-401136** **31-401137**	Modular Head Trial for Bi-polar	-6 mm -3 mm Standard +3 mm +6 mm +9 mm +12 mm
	**31-401165** **31-401164** **31-401163** **31-401162** **31-401161**	Modular Head Trial for Endo II	-6 mm -3 mm Standard +3 mm +6 mm

Tray 4 (continued)

Product	Part Number	Description	Size
	**31-165306** **31-165308** **31-165310** **31-165316** **31-165320** **31-165326** **31-165330** **31-165340**	Bi-polar Liner Removal Tool	41 mm 42 mm 43/45 mm 46/47 mm 48/50 mm 51/52 mm 53/56 mm 58/61 mm
	**31-165341**	Bi-polar Liner Removal Dumbbell	—
	**31-555611**	Cinch Modular Handle	—
	**31-401168**	Cinch Endo/Bipolar II Trial Attachment	—
	**31-555618**	Cinch Head Pusher/Impactor	—

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Date: 12/06

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, canal plugs, and acetabular augments.

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
Acetabular Augments	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 of previously failed total hip arthroplasty.

Polished Femoral Hip Prosthesis with Proximal Cement Spacer is intended for cemented use only and may be used in partial and total hip arthroplasties.

The porous titanium augments are intended to provide the orthopedic surgeon with a prosthetic alternative to structural allograft in cases of segmental deficiencies.

The porous titanium acetabular augment is affixed to the mating acetabular cup using bone cement. The assembled porous titanium augment/acetabular construct is intended for cemented or uncemented use.

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.

Porous coated devices are marketed for non-cemented use in the United States for skeletally mature patients undergoing primary hip replacement surgery as a result of non-inflammatory degenerative joint disease.

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. Laboratory testing has shown an increase in wear associated with 36mm diameter liners as compared to 32mm liners. The risks associated with the increase in wear must be weighed against the potential benefits of using the larger size liners and modular heads.
9. Porous titanium acetabular shells require the placement of all-polyethylene liners using acrylic bone cement.
10. Porous titanium augments must be attached to the acetabular shells using acrylic bone cement.

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.

In any instance where a liner engages the RingLoc® locking ring and the liner is subsequently removed or replaced, the RingLoc® locking ring should be replaced with a new ring.

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 that 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 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.
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.

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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.

NOTES

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert herein and Biomet's website.

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