

THE
ANSWER[®]
HIP SYSTEM



BIOMET[®]
ORTHOPEDICS

THE ANSWER[®]

HIP SYSTEM

Integrated A/P Spacers

Centralizes the stem in the canal and provides for a uniform cement mantle

3° Bi-Planar Taper

Promotes compressive loading of the cement mantle

Interlok[®] Finish

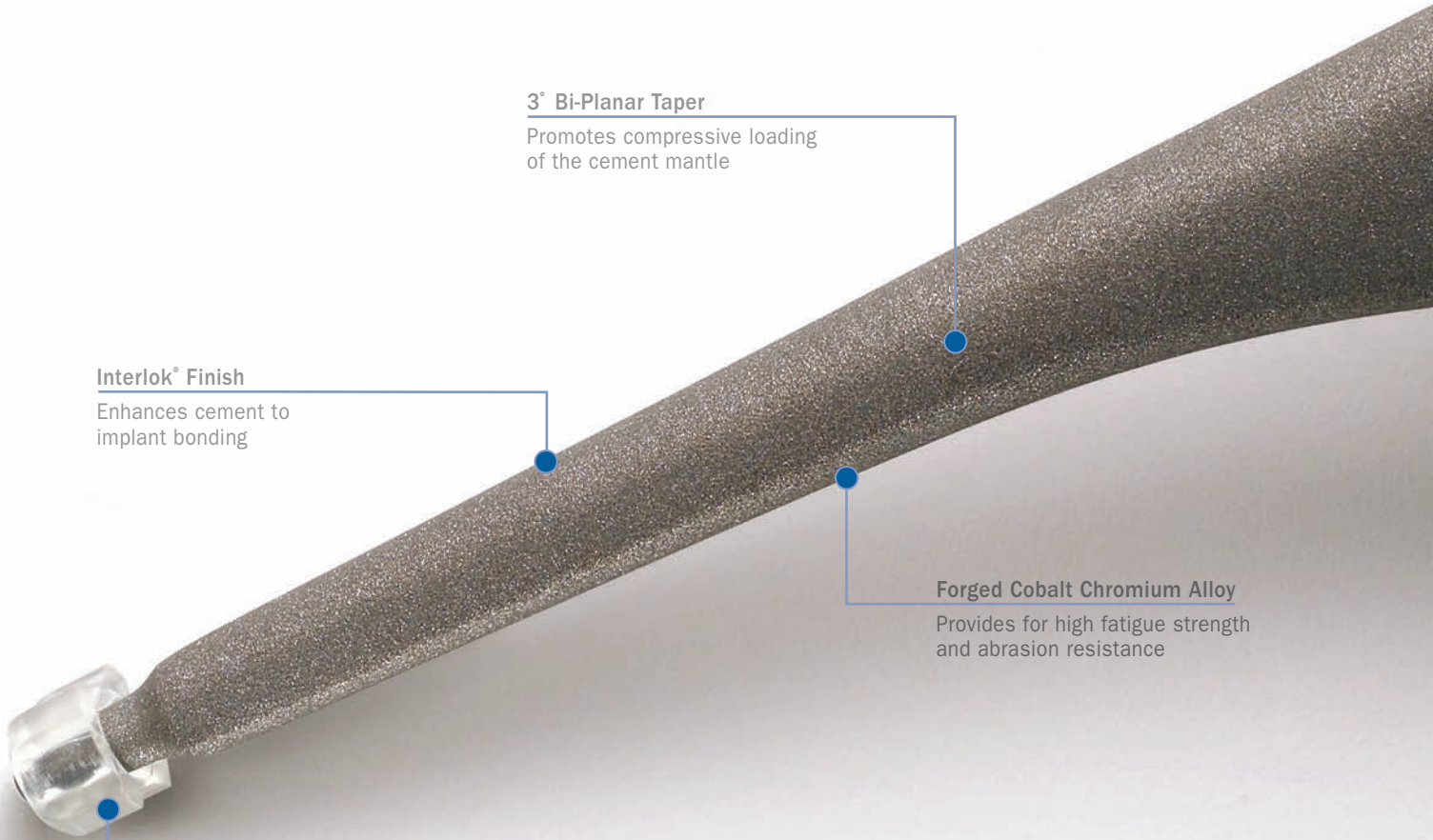
Enhances cement to implant bonding

Forged Cobalt Chromium Alloy

Provides for high fatigue strength and abrasion resistance

PMMA Distal Centralizer

Centralizes the component and provides an even 1.5mm cement mantle, 3mm circumferentially





Lateral Offset Restoration

Offset restoration with the stem is achieved by shifting the neck geometry of the implant medially 6mm while maintaining a constant neck shaft angle and slightly increasing the length of the taper

Traditional Neck Geometry

A standard Morse-type taper with reduced neck geometry facilitates optimal range of motion; adapts to seven neck lengths

Medial Collar

Stresses the medial calcar and helps prevent subsidence of the stem



COBALT™ HV BONE CEMENT AND OPTIVAC® VACUUM MIXING SYSTEMS

The Cobalt™ HV Bone Cement / Optivac® Vacuum Mixing System combination provides a consistent cement mixture for porosity reduction.¹

This leads to a stronger cement for cemented hip arthroplasty.¹ The Optivac® System was developed specifically to mix high viscosity bone cement, like Cobalt™ HV Bone Cement.

The Optivac® Vacuum Mixing System is the only system that not only mixes but also collects the cement under vacuum. This exclusive Optivac® System technology along with Cobalt™ HV Bone Cement provides:

- Reduced porosity in the cement¹
- Stronger cement mantle¹
- Improved handling characteristics¹
- Easily recognizable cement against bone
- Safer alternative in the O.R. than traditional glass ampoules

THE ANSWER[®] HIP SYSTEM

SURGICAL TECHNIQUE

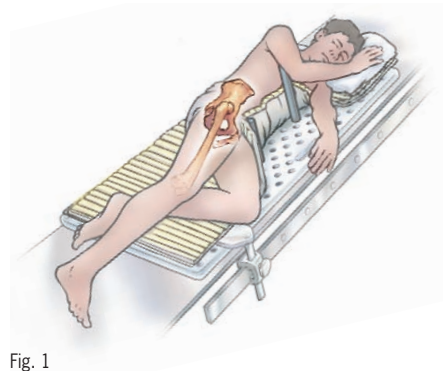


Fig. 1

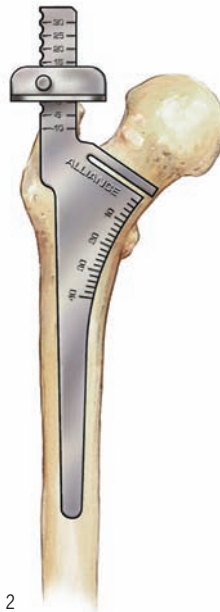


Fig. 2



Fig. 3

PATIENT POSITIONING AND SURGICAL APPROACH

The Answer[®] 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 1).

PREOPERATIVE PLANNING

Preoperative templates are provided for determining optimal component size, femoral neck resection level, appropriate neck length and offset. 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.

TEMPLATING TIPS

Intraoperative limb length measurement is an essential component of successful total hip replacement.

- Mark the apparent center of rotation of the affected hip femoral head with an "x"
- Draw a line across the ischial tuberosities, intersecting the lesser trochanters, and evaluate the level of intersection as an indication of the relative length of each hip
- Identify the level of resection and measure the distance from the resection level to the lesser trochanter; mark the level of the neck resection on the X-ray and write down the number of millimeters of the resection above the lesser trochanter

RESECTING THE FEMORAL HEAD

A broach/provisional or the femoral resection template may be used as the template for the resection level (Figure 2).

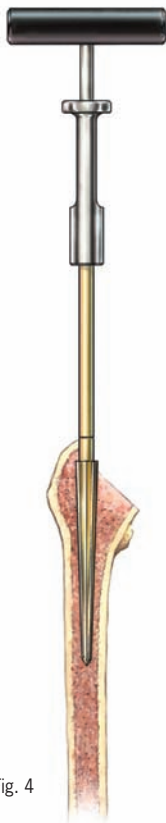


Fig. 4



Fig. 5

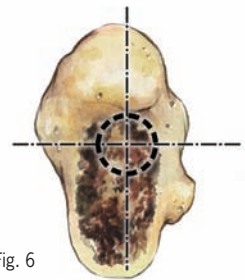


Fig. 6

ACCESSING FEMORAL CANAL

The Exact™ Offset Chisel may be used to access the piriformis fossa and clear a channel to accept the tapered reamers (Figure 3). The offset chisel design assures adequate visualization for a lateral pathway to avoid varus positioning. A starter reamer on a T-handle may be used to identify and open the femoral canal (Figure 4).

REAMING FEMORAL CANAL

The objective of reaming the canal is to provide for a planned ideal cement mantle. The Answer® stem is designed to provide a uniform minimal 1.5mm cement mantle or 3mm circumferentially.

Note: A 9mm prosthesis circumferentially has a 2mm cement mantle and sizes 11mm–17mm each have a 3mm circumferential cement mantle.

The tapered Exact™ Alliance® reamers will produce a minimum 1.5mm cement mantle envelope per side (3mm circumferentially) when used with the same size Answer® femoral component (Figure 5). Example: Ream and broach to 11mm. Implant a size 11mm Answer® stem. Begin with a canal reamer that is 3–4mm smaller than the templated femoral component. Sequentially ream the femoral canal until cortical “chatter” is encountered. It is important to stay lateral with the femoral reamers to ensure that the canal is being prepared in neutral alignment with the femoral axis (Figure 6).

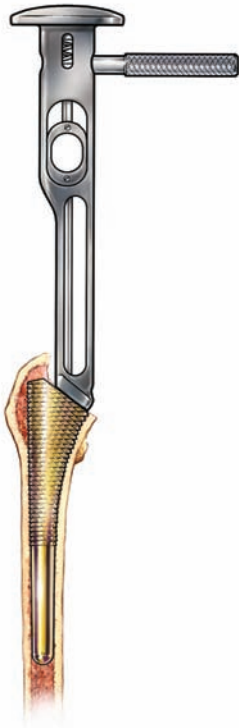


Fig. 7



Fig. 8



Fig. 9

BROACHING PROXIMAL FEMUR

Like the tapered reamers, the broach will create an envelope that will provide for a minimum of 1.5mm per side or a 3mm circumferential cement mantle. Begin the broaching process with a broach at least 2–3mm smaller than the largest reamer used. Attach the broach handle to the broach by pulling back on the trigger handle and releasing to lock it into place. It is important that the broach is oriented so as to produce the desired femoral anteversion. This will help to ensure maximum proximal canal fill. The broach is impacted until it is slightly below the level of the initial calcar cut (Figure 7). Sequentially increase the size of the broach until the templated size is reached or the broach engages the medial cortex and cannot be placed deeper. With the proper size broach in place, the calcar can be planed flush by using the Exact™ retractable calcar planer (Figure 8). The calcar planer is specially designed to reach the short broach post and to aid in the prevention of metal-to-metal wear of the post.

TRIAL REDUCTION

To perform the trial reduction with the final broach still in place, attach the Exact™ Integral® magnetic neck trunion over the extended broach post. The gold trunion indicates standard offset, while the black trunion represents lateralized offset (Figure 9). The Exact™ Integral® magnetic trunions are sized to correspond to the appropriate broach, and the stem size is clearly marked on top of the trunion. Select the trial femoral head of desired diameter and neck length. The collared trial should rest on the calcar and the rasp surface (Figure 10). Reduce the hip to ensure that proper leg length and joint stability have been achieved. If needed, additional adjustments to neck length and/or offset can be completed at this time.

Note: The Answer® hip and the Integral® hip utilize the same Exact™ magnetic neck trunions.



Fig. 10

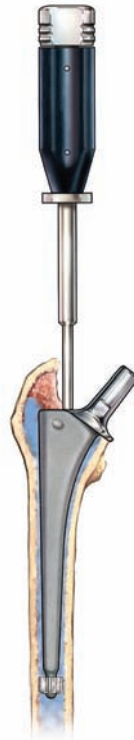


Fig. 11

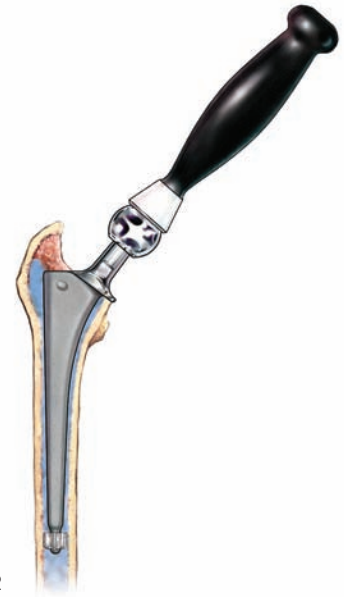


Fig. 12

CEMENT INSERTION

A Biomet® Bio-Plug™ or intramedullary bone plug component is placed in the canal to allow a 2cm cement column below the tip of the stem. The canal is then thoroughly irrigated with pulsatile irrigation and packed dry. Using the Optivac® Mixing System, inject Cobalt™ Bone Cement in a retrograde fashion and then pressurize.

FEMORAL COMPONENT INSERTION

Select the appropriate size Answer® stem that correlates with the last reamer size used. Next, slide the same size distal centralizer onto the stem. For example, an 11mm stem accepts the same size 11mm, 1.5mm centralizer sleeve. The stem is inserted placing lateral pressure to prevent varus positioning in the canal until fully seated (Figure 11). Extraneous cement is then removed. Once cement hardening is achieved, a final trial reduction may be done and the correct modular head chosen for reconstitution of leg length, lateral offset and stability can be impacted (Figure 12).

With the Answer® Hip System, a lateralized implant option is available. If additional offset is required after assessing joint stability with the proper broach in place, the lateralized provisional stem should then be inserted and another trial reduction completed. The offset will be increased by 6mm in all lateralized femoral components. This increased offset will allow soft tissue tension without changing neck resection level or the length of the leg. The lateralized stem should be inserted in the same fashion as previously described.

This surgical technique is utilized by Ernest A. Eggers, M.D., Louisville, KY. 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.

THE ANSWER[®] HIP SYSTEM

ORDERING INFORMATION

STANDARD/LATERALIZED COMPONENTS

Stem Size	Stem Length	Implant Standard	Implant Lateralized	Exact [™] Alliance [®] Broach	Exact [™] Alliance [®] Tapered Reamer
9mm	125mm	162601	162501	31-400009	31-400029
11mm	135mm	162602	162502	31-400011	31-400031
13mm	145mm	162603	162503	31-400013	31-400033
15mm	155mm	162604	162504	31-400015	31-400035
17mm	165mm	162605	162505	31-400017	31-400037

INTEGRAL[®] MAGNETIC NECK TRUNIONS

Standard (Gold)		Lateralized (Black)	
Sizes	Part #	Sizes	Part #
7–10mm	31-400022	8–10mm	31-400042
11–14mm	31-400023	11–14mm	31-400043
15–21mm	31-400024	15–21mm	31-400044

PMMA DISTAL STEM POSITIONER

Sizes	Part #	Sizes	Part #
9mm	162656	15mm	162659
10mm	162640	16mm	162643
11mm	162657	17mm	162660
12mm	162641	18mm	162644
13mm	162658	19mm	162661
14mm	162642	20mm	162646



Exact[™] Instrument Cases:

Exact[™] General Case I

595100

Exact[™] General Case II

595101

Alliance[®] Specific Cases:

Exact[™] Alliance[®] Broach Case

595105

Exact[™] Alliance[®] Tapered Reamer Case

595106

Rx90[®] Smooth Template:

Exact[™] Rx90[®] Smooth Template Standard and Lateralized

31-149097

NOTES:

Biomet Orthopedics, Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581 USA

01-50-0950
Date: 01/06

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, 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.
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, 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.

Authorized Representative: Biomet U.K., Ltd.
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CE0086

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REFERENCE:

1. Wang, J.S. et al. Is There Any Difference Between Vacuum Mixing Systems in Reducing Bone Cement Porosity? *Journal of Biomedical Materials Research*. 33(2):115-119, 1996.

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