REGENEREX™ RINGLOC®+
Modular Acetabular System

SURGICAL TECHNIQUE

BIOMET® ORTHOPEDICS

This technique is presented to demonstrate the surgical technique utilized by Michael Berend, M.D., of Mooresville, IN; and Kevin Garvin, M.D., of Omaha, NE. Biomet, as the manufacturer of this medical 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.

REGENEREX™ RINGLOC®+ MODULAR ACETABULAR SYSTEM

SURGICAL TECHNIQUE – PRIMARY PROCEDURE

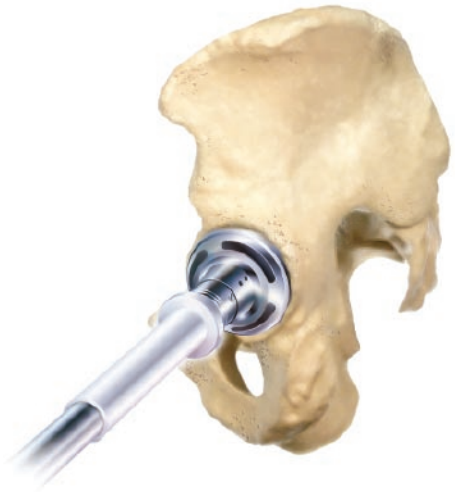


Fig. 1

ACETABULAR PREPARATION

Prepare the acetabulum utilizing acetabular reamers, while maintaining the appropriate amount of anteversion and abduction as desired (Figure 1). Often with acetabular defects in the revision setting, less reaming is necessary. Once reaming is complete, use the cup trials to confirm the position and accuracy of the reaming.

Once the desired ream has been achieved, select the implant 1–2mm larger than the final ream. Example: Ream to 54 or 55mm, implant 56mm. This will provide 1–2mm of press-fit for the implant.

Fig. 2

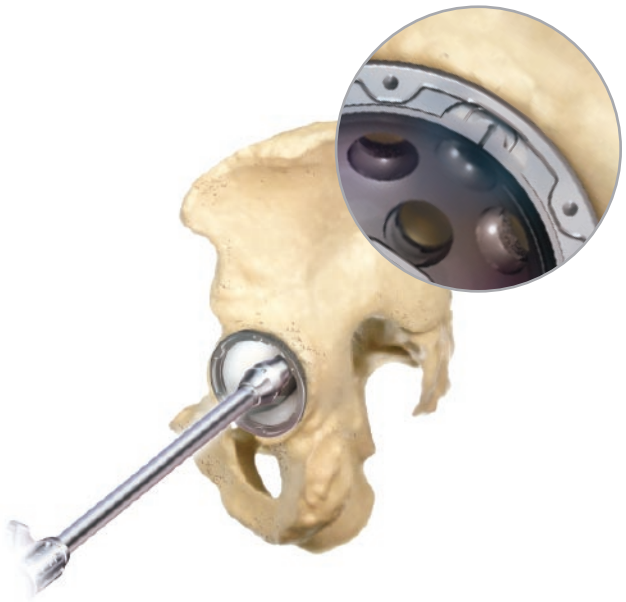


Fig. 3

SHELL INSERTION

Thread the inserter into the apical hole of the implant and impact it into the acetabulum (Figures 2 and 3). While impacting, note the position of the screw holes to obtain the optimal position for screw placement. When positioning the cup, note the placement of the liner unlock mechanism. The unlock mechanism is located between the dimpled anti-rotation tabs in all cup configurations. It should be placed superior/posterior (Figure 3). The RingLoc®+ opening is placed at the superior portion of the cup to assist with screw hole orientation.

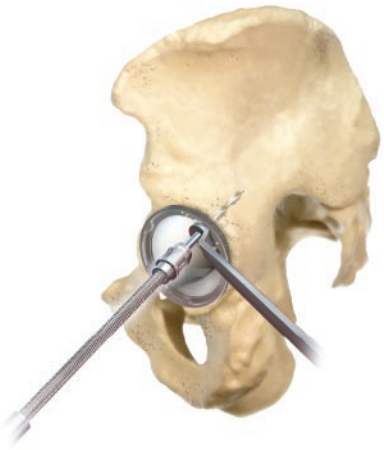


Fig. 4

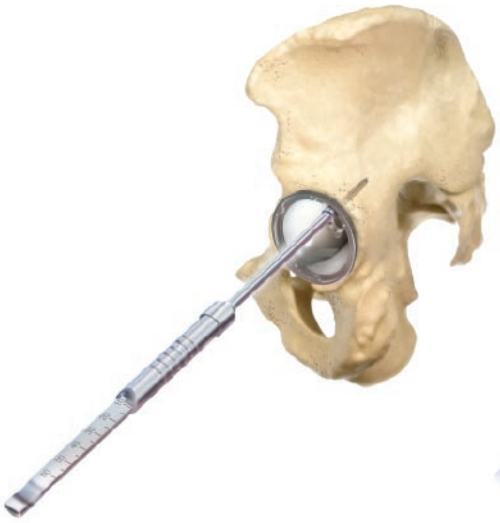


Fig. 5

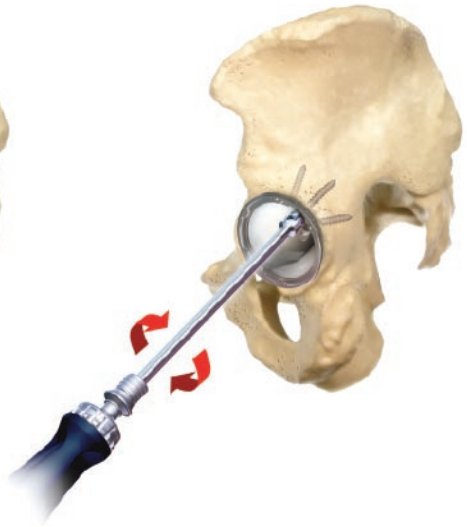


Fig. 6

SCREW INSERTION

If screw fixation is desired, use the drill guide to drill a pilot hole in the desired screw hole (Figure 4). Measure the depth of the hole with the depth gauge, select the 6.5mm screw with the corresponding length and insert it into the hole with the screwdriver (Figure 5). Place additional screws as needed (Figure 6). Inferior or ischial screw holes are present if ischial fixation is desired.

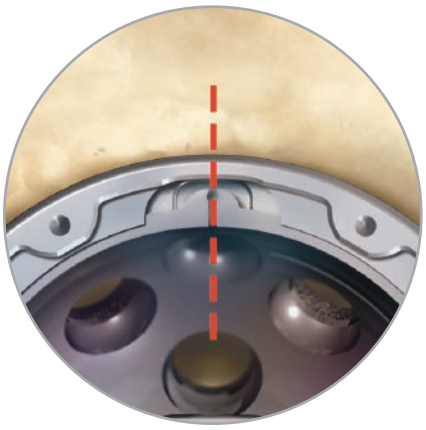


Fig. 7
Superior

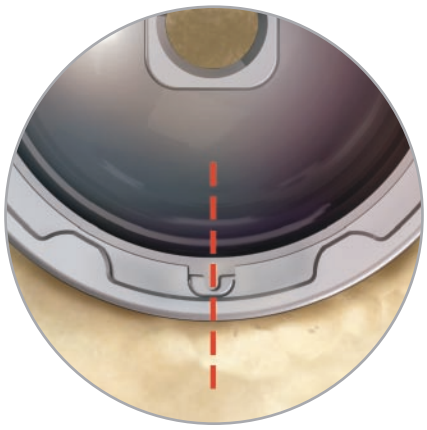


Fig. 8
Inferior

RING ALIGNMENT

Prior to inserting the liner, verify that the locking ring is properly aligned as shown in Figures 7 and 8. Liner trials or the appropriately sized polyethylene liner can be used before trialing the neck length for the femoral component. **NOTE: After impacting the polyethylene, the ring should rotate freely side to side (with probe).**

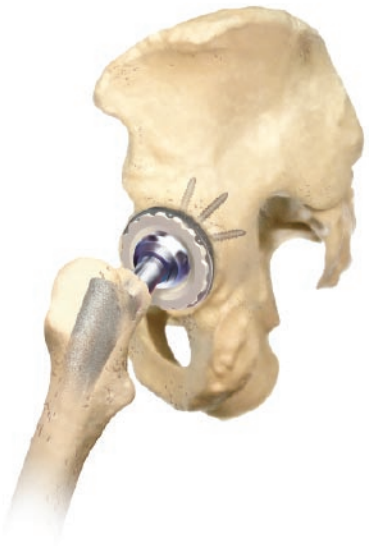


Fig. 9

TRIAL REDUCTION

Once the liner is locked into the final position, a trial or final femoral reduction can be performed (Figure 9).

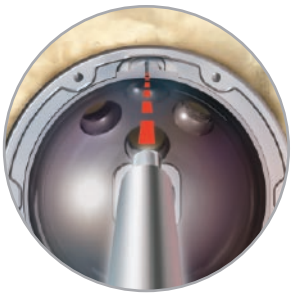


Fig. 11

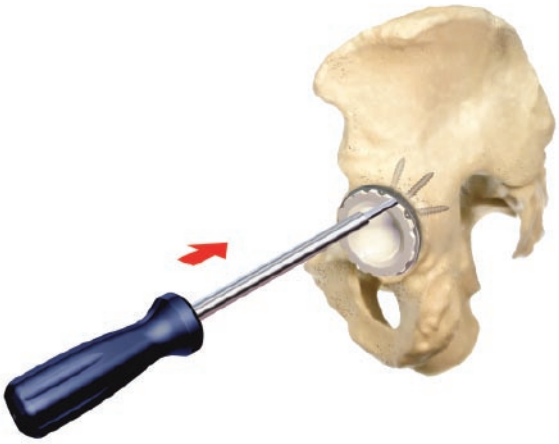


Fig. 10

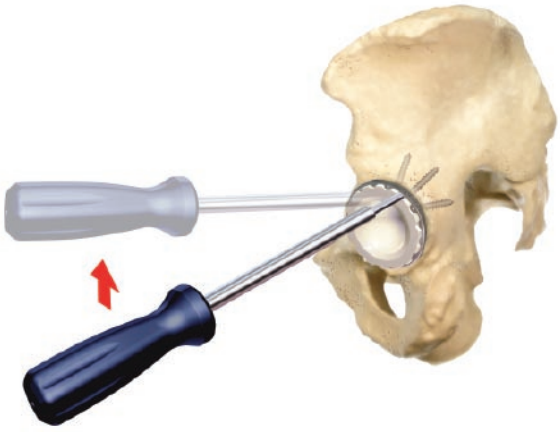


Fig. 12

LINER REVISION

If it is necessary to remove the liner from the cup, the liner removal tool can be used to open the ring and then lever out the liner. To remove a liner, insert the liner removal tool into the cup as shown in Figures 10, 11 and 12. The insertion of the tool will expand the lock ring. Lever the handle of the tool outward **while maintaining downward pressure with the tool.**

NOTE: Anytime the liner is removed, it is recommended that the locking ring is removed and replaced with a new one. If the liner is damaged in any way, a new liner should be utilized.

REGENEREX™ RINGLOC®+ MODULAR ACETABULAR SYSTEM

SURGICAL TECHNIQUE – REVISION PROCEDURE

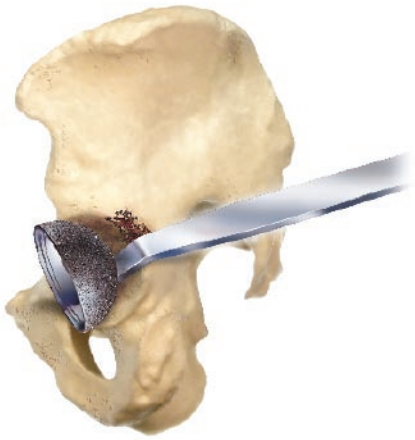


Fig. 1

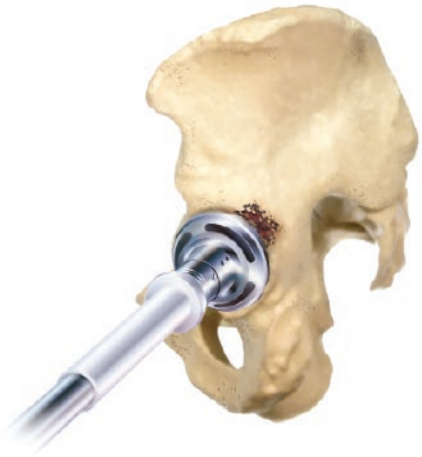


Fig. 2

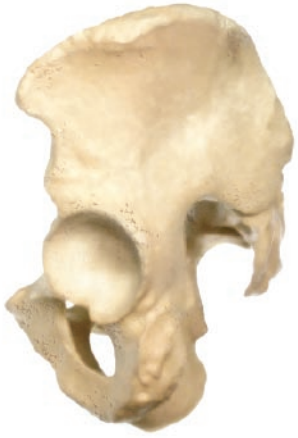


Fig. 3

ACETABULAR PREPARATION

Remove existing acetabular component(s) using contemporary techniques, conserving as much bone as possible (Figure 1). Once the component is removed, careful evaluation of the acetabulum is suggested, with close attention to the integrity of the anterior/posterior columns and the medial wall. Curette and irrigate any osteolytic cysts.

Prepare the acetabulum with acetabular reamers, maintaining the appropriate amount of anteversion and abduction as desired (Figure 2). Ream only the amount of bone necessary to create an adequate hemispherical cavity for support of an acetabular shell, while maintaining the integrity of both columns and the medial wall (Figure 3). **NOTE: The final implant should be 2mm larger than the last reamer size used.**

Once the acetabulum has been evaluated, it should be decided whether or not augmentation of the acetabular shell is necessary. The trial shell can be utilized to determine stability with anterior-posterior and superior-inferior displacement which simulates cup stability. If it is decided to utilize augmentation, the augment should be placed before implanting the acetabular shell.

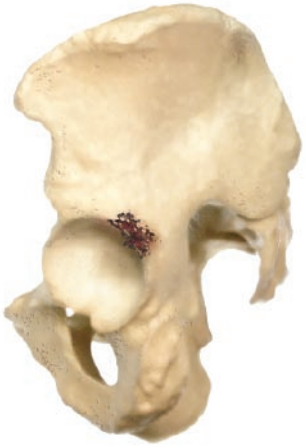


Fig. 4

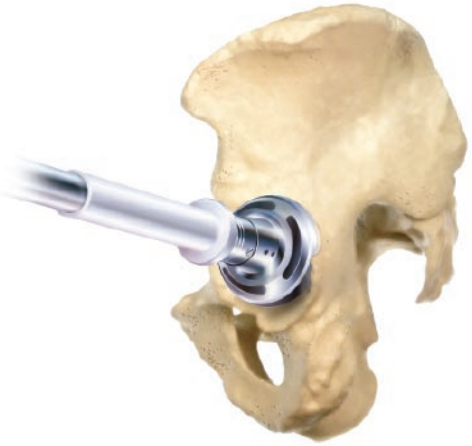


Fig. 5

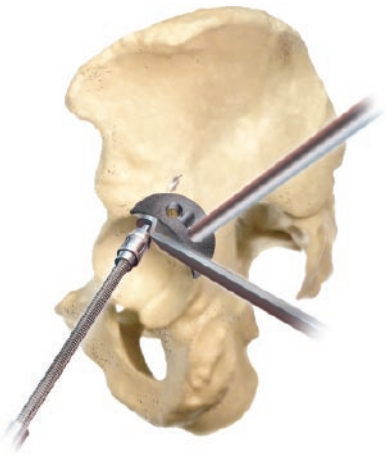


Fig. 6

AUGMENT PLACEMENT

If augmentation of the acetabulum is required, it will be necessary to prepare the site for augment placement (Figure 4). The defect can be prepared using acetabular reamers to match the corresponding augment size (52–58mm, 2mm increments) (Figure 5). Posterior defects should be carefully prepared to protect the sciatic nerve if reamers are utilized. Once the defect has been prepared, use the augment provisionals to determine the necessary size to fill the defect and aid in cup stability. **NOTE: Augment provisionals have an offset inner surface when compared with the final implant. This offset is 2mm and will replicate the spacing required for the cement mantle.**

Once the augment size is determined, place the implant, utilizing the augment holding instrument and a shell gauge. The shell gauge is designed to allow for proper sizing of the augment and cup implant. The shell gauge is windowed, allowing for visualization of augment placement with respect to desired cup position. Use the drill guide to drill a pilot hole in the desired screw hole (Figure 6). Measure the depth of the hole with the depth gauge, select the 6.5mm screw with the corresponding length and insert it into the hole with the screwdriver (Figure 7). Additional screws can also be placed for added stability of the implant.

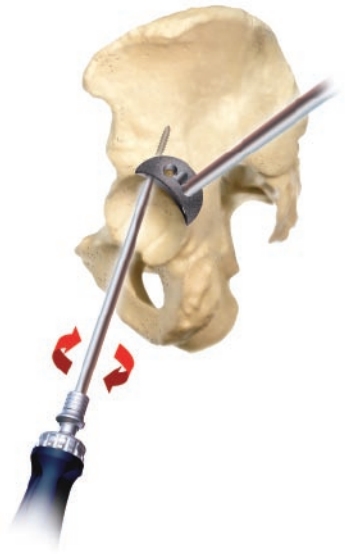


Fig. 7

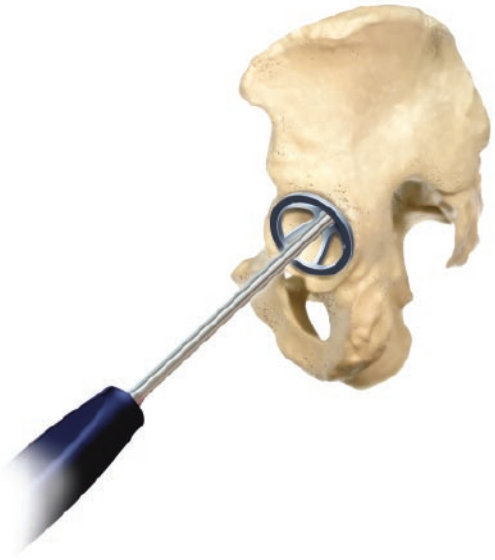


Fig. 8a
without augment

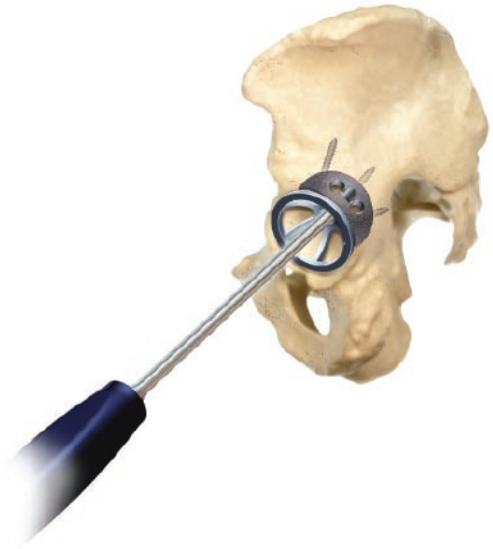


Fig. 8b
with augment

SHELL SIZING AND POSITIONING

After the acetabulum has been prepared, it is necessary to evaluate the stability of the implants by using the shell gauges (Figures 8a and 8b). The shell gauge used should match the size of the last reamer used. The final implant should be 2mm larger than the last reamer used.

EXAMPLE: If the last reamer size used is 60mm, utilize a 60mm trial and the final implant should be 62mm. This will provide a 2mm press fit.

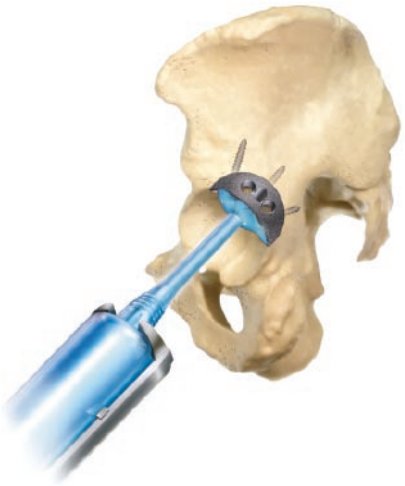


Fig. 9

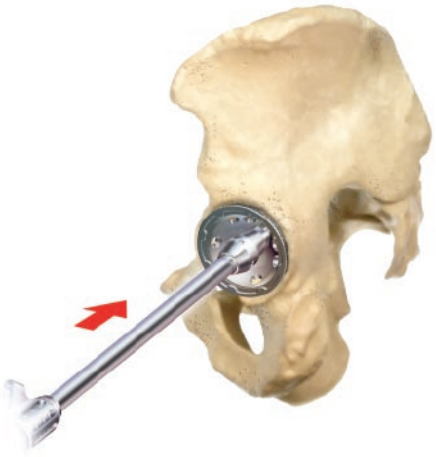


Fig. 10a

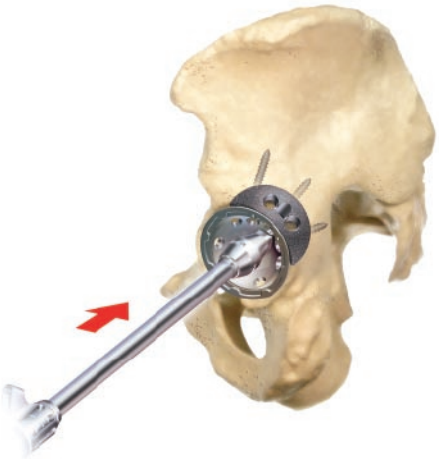


Fig. 10b

SHELL INSERTION

If augments were used, a 1–2mm layer of bone cement is required between the cup and the augment(s). Prior to cementing, bone graft can be inserted into remaining cavitary defects. Place cement on the inferior surface of the augment prior to placement of the shell (Figure 9).

Prior to inserting the liner, verify that the locking ring is properly aligned. Liner trials or the appropriately sized polyethylene liner can be used before trialing the neck length for the femoral component. Impact the shell (Figures 10a and 10b). **NOTE: Do not use ball impactors to seat implant.**

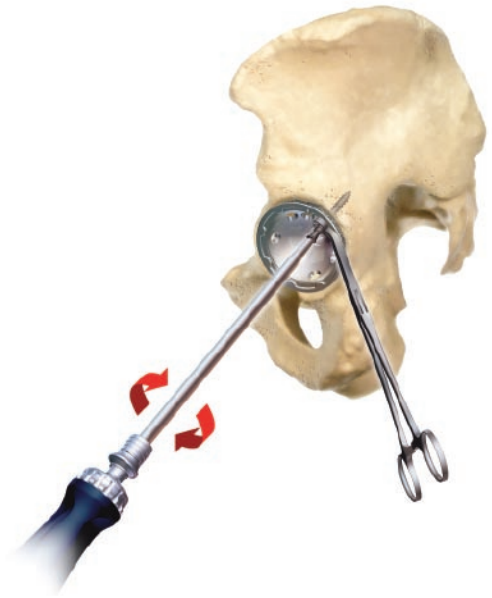


Fig. 11

SCREW INSERTION

If screw fixation is desired, use the drill guide to drill a pilot hole in the desired screw hole. Measure the depth of the hole with the depth gauge, select the 6.5mm screw with the corresponding length and insert it into the hole with the screwdriver (Figure 11). Place additional screws as needed.

REGENEREX™ RINGLOC®+ MODULAR ACETABULAR SYSTEM

ORDERING INFORMATION – IMPLANTS

REGENEREX™ RINGLOC®+ SOLID SHELL ACETABULAR COMPONENTS*

Implant Image	Implant Part #	Implant Style Provisional #	Shell Gauge #	Description	Size
	**PT-104048**	31-400648	31-177948	REGENEREX/RNGL+ SOLID	48MM SZ 22
	PT-104050	31-400650	31-177950	REGENEREX/RNGL+ SOLID	50MM SZ 22
	PT-104052	31-400652	31-177952	REGENEREX/RNGL+ SOLID	52MM SZ 23
	PT-104054	31-400654	31-177954	REGENEREX/RNGL+ SOLID	54MM SZ 23
	PT-104056	31-400656	31-177956	REGENEREX/RNGL+ SOLID	56MM SZ 24
	PT-104058	31-400658	31-177958	REGENEREX/RNGL+ SOLID	58MM SZ 24
	PT-104060	31-400660	31-177960	REGENEREX/RNGL+ SOLID	60MM SZ 25
	PT-104062	31-400662	31-177962	REGENEREX/RNGL+ SOLID	62MM SZ 25
	PT-104064	31-400664	31-177964	REGENEREX/RNGL+ SOLID	64MM SZ 26
	PT-104066	31-400666	31-177966	REGENEREX/RNGL+ SOLID	66MM SZ 26

Please refer to the Biomet Price Guide for even sized 42–80mm implant style provisionals and shell gauge sizes 40–80mm.
*One apical plug packaged with each solid shell.

REGENEREX™ RINGLOC®+ LIMITED-HOLE ACETABULAR COMPONENTS

Implant Image	Implant Part #	Implant Style Provisional #	Shell Gauge #	Description	Size
	**PT-116048**	31-400648	31-177948	REGENEREX/RNGL+ LTD	48MM SZ 22
	PT-116050	31-400650	31-177950	REGENEREX/RNGL+ LTD	50MM SZ 22
	PT-116052	31-400652	31-177952	REGENEREX/RNGL+ LTD	52MM SZ 23
	PT-116054	31-400654	31-177954	REGENEREX/RNGL+ LTD	54MM SZ 23
	PT-116056	31-400656	31-177956	REGENEREX/RNGL+ LTD	56MM SZ 24
	PT-116058	31-400658	31-177958	REGENEREX/RNGL+ LTD	58MM SZ 24
	PT-116060	31-400660	31-177960	REGENEREX/RNGL+ LTD	60MM SZ 25
	PT-116062	31-400662	31-177962	REGENEREX/RNGL+ LTD	62MM SZ 25
	PT-116064	31-400664	31-177964	REGENEREX/RNGL+ LTD	64MM SZ 26
	PT-116066	31-400666	31-177966	REGENEREX/RNGL+ LTD	66MM SZ 26

Please refer to the Biomet Price Guide for even sized 42–80mm implant style provisionals and shell gauge sizes 40–80mm.

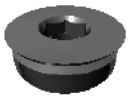
REGENEREX™ RINGLOC®+ MULTI-HOLE ACETABULAR COMPONENTS

Implant Image	Implant Part #	Implant Style Provisional #	Shell Gauge #	Description	Size
	**PT-106054**	31-400654	31-177954	REGENEREX/RNGL+ MULTI	54MM SZ 23
	PT-106056	31-400656	31-177956	REGENEREX/RNGL+ MULTI	56MM SZ 24
	PT-106058	31-400658	31-177958	REGENEREX/RNGL+ MULTI	58MM SZ 24
	PT-106060	31-400660	31-177960	REGENEREX/RNGL+ MULTI	60MM SZ 25
	PT-106062	31-400662	31-177962	REGENEREX/RNGL+ MULTI	62MM SZ 25
	PT-106064	31-400664	31-177964	REGENEREX/RNGL+ MULTI	64MM SZ 26
	PT-106066	31-400666	31-177966	REGENEREX/RNGL+ MULTI	66MM SZ 26
	PT-106068	31-400668	31-177968	REGENEREX/RNGL+ MULTI	68MM SZ 27
	PT-106070	31-400670	31-177970	REGENEREX/RNGL+ MULTI	70MM SZ 27
	PT-106072	31-400672	31-177972	REGENEREX/RNGL+ MULTI	72MM SZ 28

Please refer to the Biomet Price Guide for even sized 42–80mm implant style provisionals and shell gauge sizes 40–80mm.

An Implant Style Provisional or Shell Gauge can be used for trialing. It is not necessary to use both.
RingLoc® liner trials are also available. Please refer to the Biomet Price Guide for ordering information.

ORDERING INFORMATION – IMPLANTS, CONTINUED

Image	Part Number	Description	Size
	**123741**	3/8–24 Apical Hole Plug*	–
	**106021** **106022** **106023** **106024** **106025** **106026** **106027** **106028**	RingLoc®+ Replacement Ring RingLoc®+ Replacement Ring RingLoc®+ Replacement Ring RingLoc®+ Replacement Ring RingLoc®+ Replacement Ring RingLoc®+ Replacement Ring RingLoc®+ Replacement Ring RingLoc®+ Replacement Ring	Size 21 Size 22 Size 23 Size 24 Size 25 Size 26 Size 27 Size 28

*One apical plug packaged with each solid shell.

LINER SIZE GUIDE

Regenerex™ RingLoc®+ Cup Size	Liner Size
42mm	20
44mm	20
46mm	21
48mm	22
50mm	22
52mm	23
54mm	23
56mm	24
58mm	24
60mm	25
62mm	25
64mm	26
66mm	26
68mm	27
70mm	27
72mm	28
74mm	28
76mm	28
78mm	28
80mm	28

ORDERING INFORMATION – INSTRUMENTS

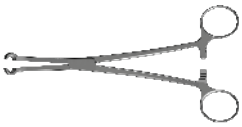
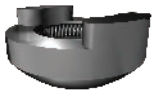
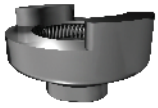
Image	Part Number	Description	Size
	420048 **420049**	Straight Hex Ratchet Shaft Straight Hex Ratchet Shaft	2.5mm 3.5mm
	**424417**	Screw Forceps	–
	**31-424200**	Modular Ratchet Handle	–
	**31-424201** **31-424202**	U-Joint Driver U-Joint Driver	2.5mm 3.5mm
	**31-111114**	Flexible Depth Gauge	–
	**31-424203**	2-in-1 Drill Guide	2.8mm & 3.2mm
	**31-424205**	Dual Angle Drill Guide	3.2mm
	**31-424204**	RingLoc®+ Quick Connect Flexible Drill Shaft	–
	**31-282815/80** **31-323215/80**	RingLoc®+ Quick Connect Drill Bits RingLoc®+ Quick Connect Drill Bits	2.8mm 3.2mm
	**31-111128** **31-111132** **31-111136** **31-111138** **31-111140**	Liner Impactor Liner Impactor Liner Impactor Liner Impactor Liner Impactor	28mm 32mm 36mm 38mm 40mm
	**31-434547**	Fixed Version Guide Lateral	–
	**S313135**	Mag Hndl Adapter Multi Tool	–
	**31-400600**	MIH Cup Inserter Handle – Modular	–
	**31-400602**	MIH Cup Inserter Handle Tip – Spherical (3/8)	–
	**31-400604**	MIH RingLoc®+ Cup Inserter Handle – Square Tip (1/4)	–
	**31-400605**	MIH Handle 1/4 Thread Insert	–

Image	Part Number	Description	Size
	**S313141**	Straight Magnum Inserter Handle	–
	**S313142** **S313144**	Straight Mag Handle Threaded Rod Kit Straight Mag Handle Threaded Rod Kit	Square tip – 1/4 Square tip – 3/8
	**S313145**	Straight Mag Handle Tip – Spherical	–
	**31-478350**	Universal Thread Extractor	–
	**31-424206** **31-424207**	Liner Removal Tool Liner Removal Tool	Inr sz 21–28 Inr sz 20
	**31-177901**	Shell Gauge Handle	–
	**31-400620** **31-400621** **31-400622** **31-400623** **31-400624** **31-400625** **31-400626** **31-400627** **31-400628**	RingLoc®+ Impactor Plate RingLoc®+ Impactor Plate RingLoc®+ Impactor Plate RingLoc®+ Impactor Plate RingLoc®+ Impactor Plate RingLoc®+ Impactor Plate RingLoc®+ Impactor Plate RingLoc®+ Impactor Plate RingLoc®+ Impactor Plate	Size 20 Size 21 Size 22 Size 23 Size 24 Size 25 Size 26 Size 27 Size 28
	595624	RingLoc® Instrument Case Shell (w/lid)	–
	595620	RingLoc® Insertion and Screw Instrument Case (w/lid)	–
	595621	RingLoc® Provisional and Reamer Inst Case (w/lid)	–
	595622	RingLoc® Liner and Head Trial Instrument Case (w/lid)	–
	595623	RingLoc® General Inst Case (w/lid)	–
	595627	RingLoc® Tag Set - General Instruments	–
	595629	RingLoc® Tag Set - 28mm Liner Trials	–
	595630	RingLoc® Tag Set - 32mm Liner Trials	–
	595631	RingLoc® Tag Set - 36mm Liner Trials	–
	595632	RingLoc® Tag Set - 38mm Liner Trials	–
	595633	RingLoc® Tag Set - 40mm Liner Trials	–

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01-50-0961
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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, and 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. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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 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:

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

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