
regenerex™
porous titanium construct
BIOMET®
ORTHOPEDICS

Clinically Proven Material

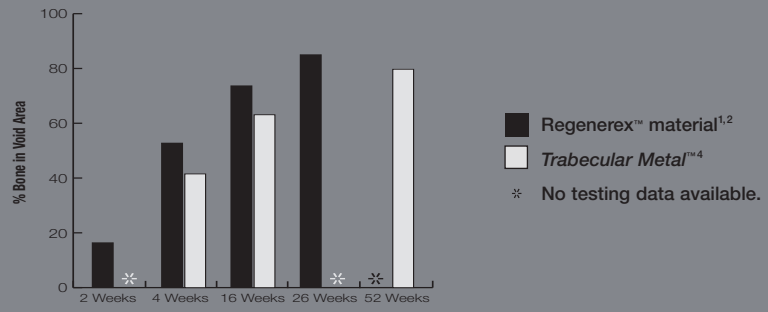
ADVANCED POROUS TECHNOLOGY

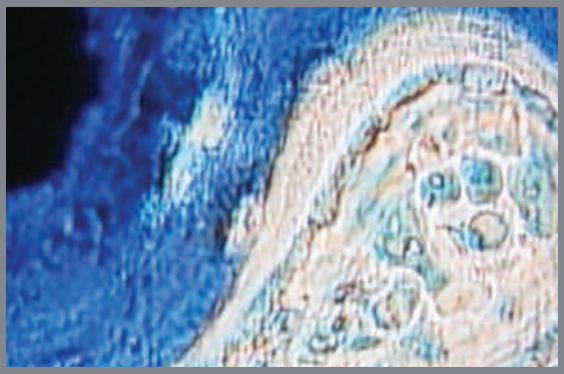
Uniting the proven clinical history of titanium with an enhanced interconnecting pore structure, Regenerex™ Porous Titanium Construct is a revolutionary technology engineered for rapid bone ingrowth. Two weeks after insertion, Regenerex™ implants have displayed bony integration and vascularization.[1,2]

INTEGRATION WITHIN WEEKS

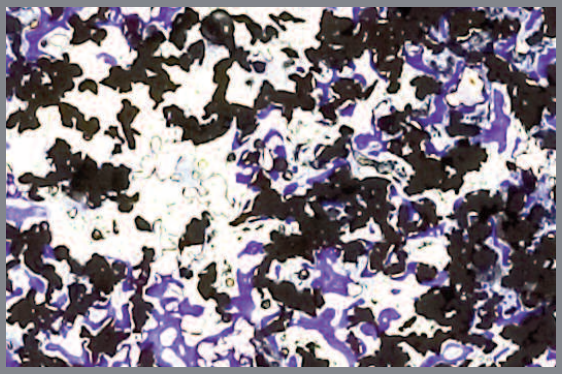
BONE INGROWTH[3]

In similar canine studies, Regenerex™ material demonstrated more rapid ingrowth[1,2] than Zimmer's *Trabecular Metal*.™[4]





Magnified view of bony apposition to Regenerex™ material four weeks after implantation into canine femur. The presence of osteocytes indicates the maturity of bone within the Regenerex™ implant. The other elements are supporting structures for healthy bone metabolism.[1,2]



Bone infiltration into 5mm diameter Regenerex™ construct four weeks after canine femur implantation.[1,2]

TITANIUM CONSTRUCT WITH 35 YEARS OF CLINICAL USE

PROVEN HISTORY OF TITANIUM

- Titanium has been used clinically for more than 35 years[5] and is proven to be extremely biocompatible.[6]
- The Regenerex™ material is manufactured from the same titanium alloy used in Biomet's clinically proven PPS® Porous Plasma Spray.[7-9]

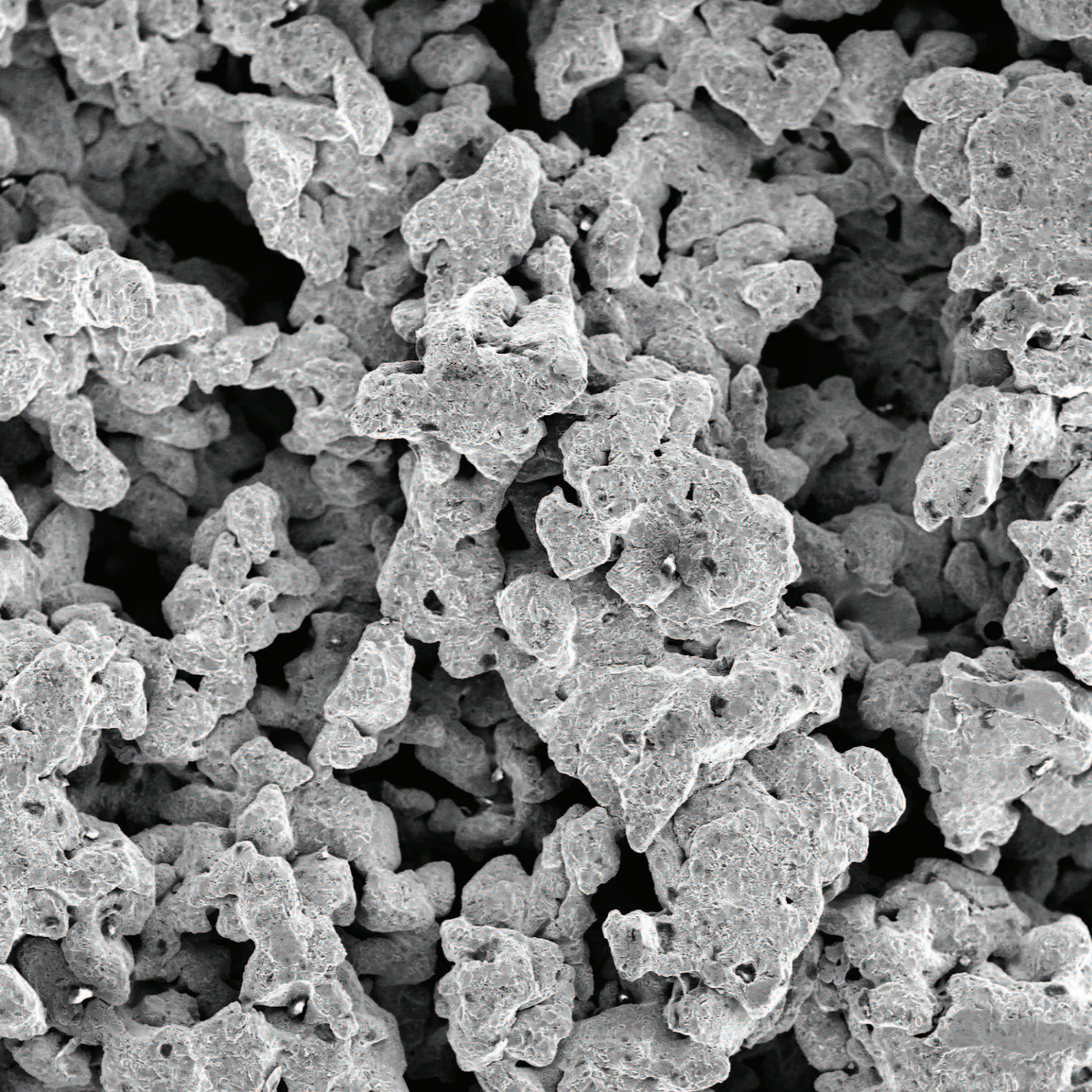
OPTIMUM PORE STRUCTURE FOR RAPID BONE INGROWTH

HIGH POROSITY

- Average porosity of 67%.[1]
- Optimized for vascularized osteogenesis.[10]
- Consistency of the construct's porosity is achieved by utilizing proprietary manufacturing processes.

OPTIMAL PORE SIZE RANGE

- A pore size of at least 100 microns is necessary for cell migration, while vascularization occurs in pore sizes greater than 300 microns.[10]
- Pore size within the Regenerex™ structure ranges from 100 to 600 microns with an average pore size of 300 microns.[1]

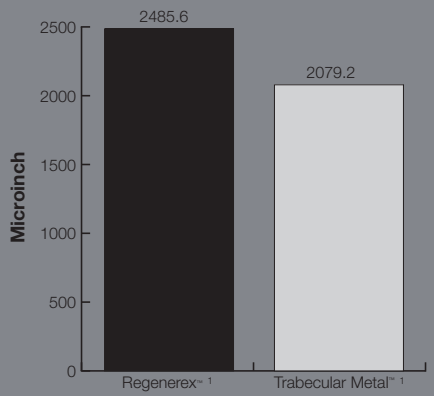


INITIAL STABILITY

ROUGHER THAN *TRABECULAR METAL*™

- 16% rougher than *Trabecular Metal*,™[1] the initial scratch-fit stability and fixation of Regenerex™ implants is well-suited for acetabular reconstruction.

AVERAGE ROUGHNESS (Ra)

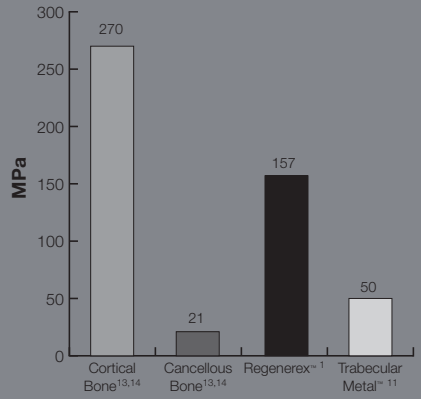


STRONG,
YET FLEXIBLE

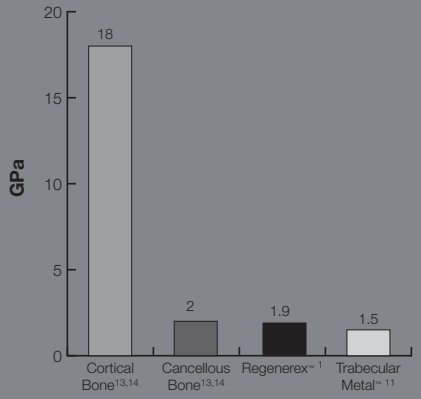
STRONGER THAN *TRABECULAR METAL*™

- The Regenerex™ construct is 300% stronger than *Trabecular Metal*™[1,11] under compressive loads, which comprise the forces most often seen in the acetabulum after total hip arthroplasty.[12]
- Maintains a strong construct without increasing the stiffness of the implant.
- Maintains a low modulus[1] with a structure similar to bone.

PEAK COMPRESSIVE STRESS



COMPRESSIVE MODULUS



INTRAOPERATIVE FLEXIBILITY

REGENEREX™ ACETABULAR AUGMENTS

- Augments can be used with any Regenerex™ shell, RingLoc® acetabular component, or M²a-Magnum™ metal-on-metal component.
- Designed to help maximize the stability of acetabular components.
- Available in 12 sizes, each with multiple holes to maximize intraoperative fixation.
- Unique design offers the option to stack augments in the most complex reconstruction cases.

REGENEREX™ ACETABULAR SHELLS

- Designed to accept a cemented all-poly cup.
- A 5mm shell wall of Regenerex™ material is designed to minimize stiffness and maximize ingrowth potential.
- Shells accommodate up to 15, 6.5mm bone screws to aid in fixation.
- Shells are available from 54mm to 76mm in 2mm increments.

SURGICAL TECHNIQUE

This technique is presented to demonstrate the surgical technique utilized by Keith R. Berend, M.D., of New Albany, Ohio; and K. David Moore, M.D., of Birmingham, Alabama. 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.

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. Any osteolytic cysts should be curetted and irrigated.

The acetabulum should be prepared with acetabular reamers, while maintaining as anatomic a position as possible (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. This can be determined by evaluating the stability of the shell provisional. If it is decided to utilize augmentation, the augment should be placed before implanting the acetabular shell.

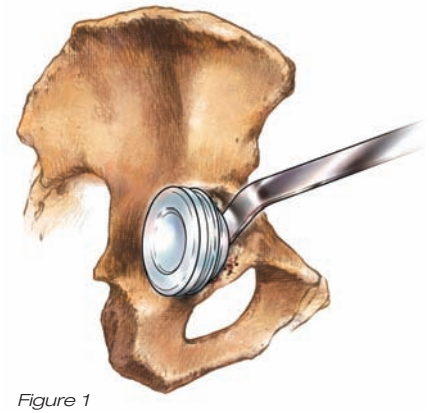


Figure 1

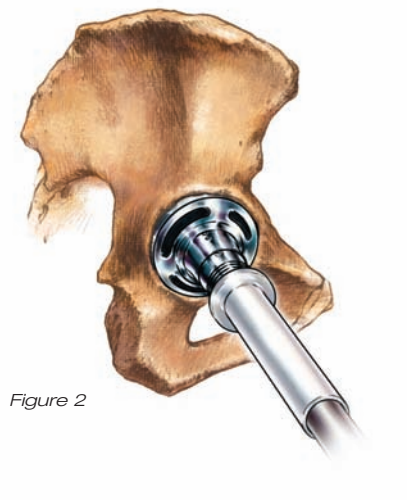


Figure 2

Figure 3

AUGMENT PLACEMENT

If it is determined that 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). 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 drill a pilot hole using the drill guide 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.

Figure 4

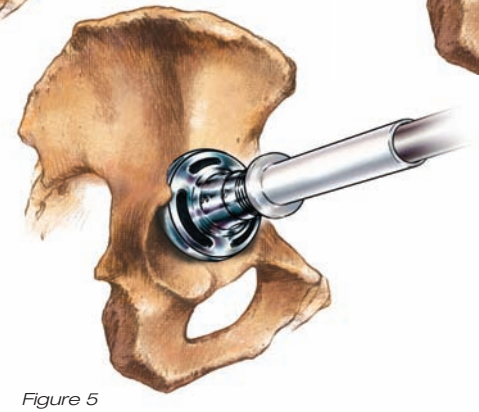


Figure 5

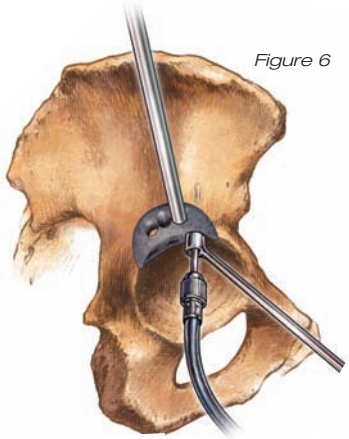


Figure 6

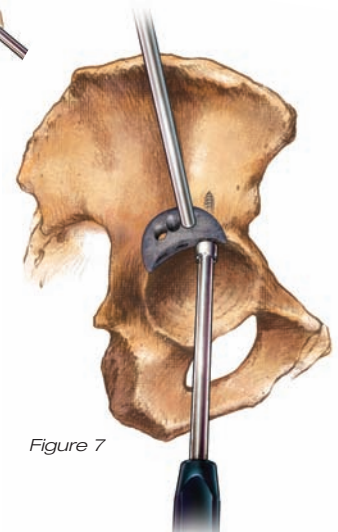


Figure 7

SHELL SIZING AND POSITIONING

After the acetabulum has been prepared, it is necessary to evaluate the stability of the implants by using the cup provisionals (Figures 8a and 8b). The cup provisional 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.

INSTRUMENT ASSEMBLY

Attach the appropriate impactor plate (small, medium, large, and x-large) to the inserter handle. Then, attach the dome that corresponds to the implant size used (e.g. use a medium impactor plate and a 60 dome for a 60mm cup) (Figure 9). The impaction dome will only work with the correct impactor plate. The implant is then placed onto the impactor plate and the knob on the handle is rotated clockwise until resistance is felt. The instrument should now solidly hold the implant. For plate removal, the handle knob should be loosened and the forked removal/multi-tool should be inserted into the gap between the plate and handle. The tool should then be levered to disengage the plate. **NOTE: Ball bearings must be exposed for plate attachment.**

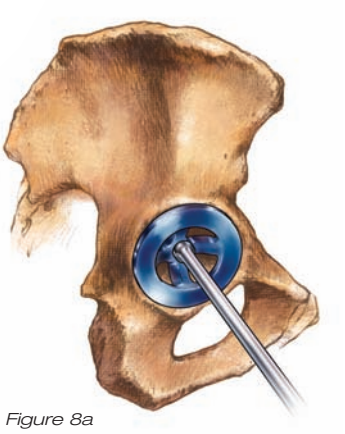


Figure 8a
without augment

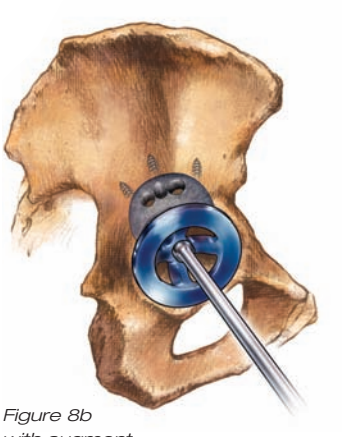


Figure 8b
with augment

Figure 9

SHELL INSERTION

If augments were used, a 1–2mm layer of bone cement is required between the cup and the augment(s). The cement should be placed on the inferior surface of the augment prior to placement of the shell (Figure 10).

Orient the shell, using the etch on the cup face, in a position that allows for the desired screw position while maintaining desired cup position. The etching represents the center of the cluster screw hole pattern. Impact the shell (Figures 11a and 11b). **NOTE: Do not use ball impactors to seat implant.**

SCREW INSERTION

If screw fixation is desired, drill a pilot hole using the drill guide 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 12). A torque limiting screwdriver is recommended. Place additional screws as needed. Bone wax may be used to fill both the unused screw holes and the screw heads. This may assist in removing the screws if future need arises.

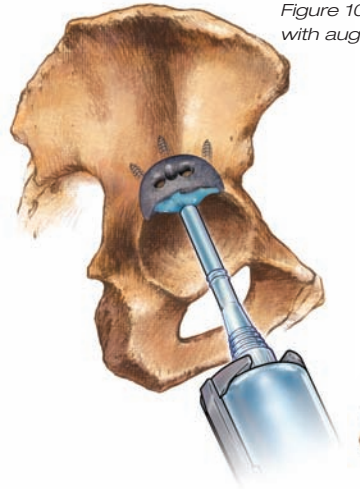


Figure 10
with augment

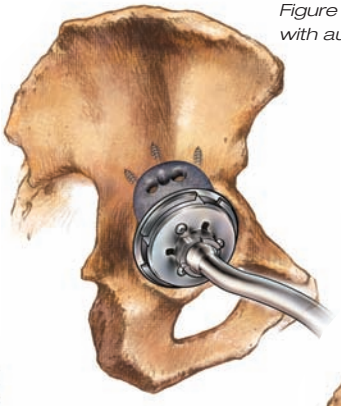


Figure 11b
with augment

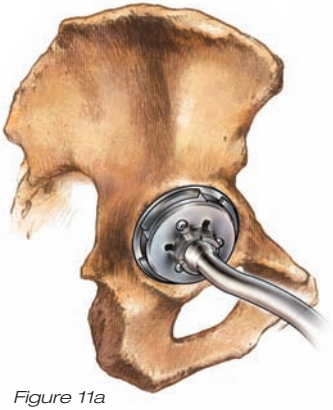


Figure 11a
without augment

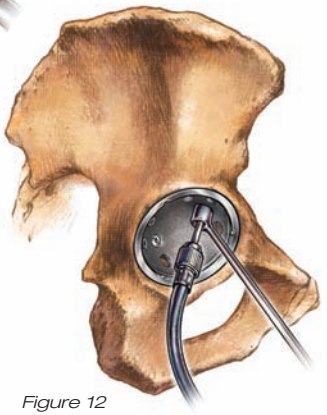


Figure 12
without augment

LINER TRIALING SYSTEM (OPTIONAL)

If a trial reduction of the femoral component is necessary before the all-poly cup is cemented in place, insert the corresponding liner trial into the implanted cup or cup provisional to determine optimal liner position and neck length (Figure 13). The liner position can be adjusted by loosening the apical screw and moving the plastic dome.

LINER INSERTION AND PLACEMENT

Apply bone cement in a doughy state to the inside of the acetabular shell (Figure 14). Insert the appropriately sized polyethylene liner, using the appropriate liner/cement technique for the liner used (Figure 15).

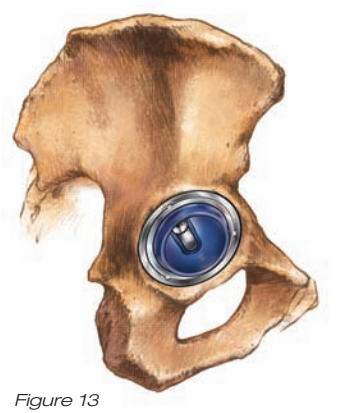


Figure 13

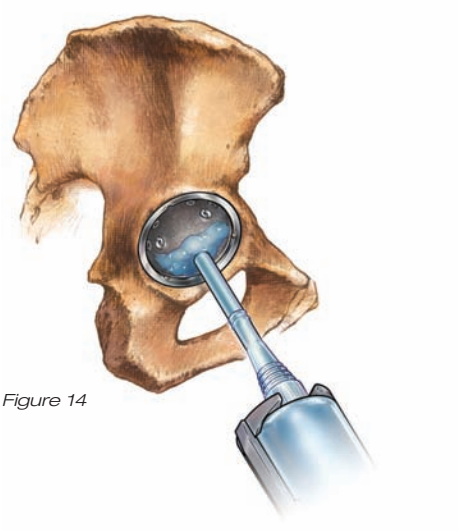


Figure 14

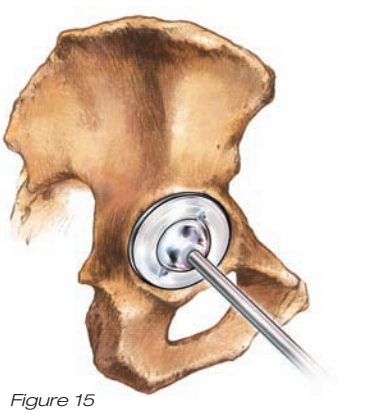


Figure 15

LINER INSERTION AND PLACEMENT (CONTINUED)

With the shell implanted and liner securely cemented in place, the construct is ready for trial reduction with the femoral component (Figures 16a and 16b).

CEMENTING ALL-POLY CUPS

RANAWAT/BURSTEIN® CEMENTED ALL-POLY CUPS/FREEDOM® CONSTRAINED ALL-POLY CUPS:

The polyethylene spacer pegs in the dome of the outer cup will not bottom out against the shell. The pegs are only 2mm in depth and are designed to rest on a 1mm bed of cement, not the shell. All excess bone cement should be removed from around the liner and shell components. This will maintain a 3mm cement mantle supporting the liner.

BIO-CLAD™ CEMENTED PRIMARY SERIES CUPS/TRI-POLAR ALL-POLY CUPS:

The polyethylene spacer pegs in the dome of the outer cup should contact the inner cup surface. The pegs measure 3mm in length and are designed to create a 3mm cement mantle to support the liner. All excess bone cement should be removed from around the liner and shell components.

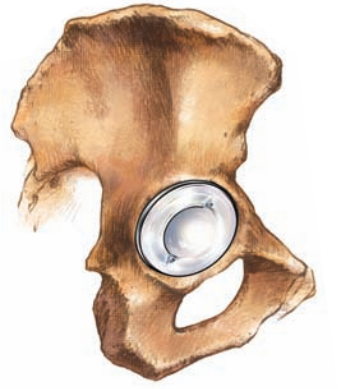


Figure 16a
without augment

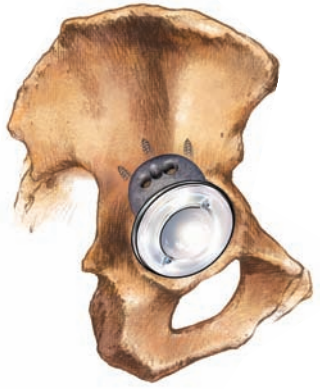


Figure 16b
with augment

ORDERING INFORMATION

Regenerex™ Revision Shells		
Implant	**Trial**	**Description**
PT-124454	31-177954	54mm OD x 44mm ID
PT-124656	31-177956	56mm OD x 46mm ID
PT-124858	31-177958	58mm OD x 48mm ID
PT-125060	31-177960	60mm OD x 50mm ID
PT-125262	31-177962	62mm OD x 52mm ID
PT-125464	31-177964	64mm OD x 54mm ID
PT-125666	31-177966	66mm OD x 56mm ID
PT-125868	31-177968	68mm OD x 58mm ID
PT-126070	31-177970	70mm OD x 60mm ID
PT-126272	31-177972	72mm OD x 62mm ID
PT-126474	31-177974	74mm OD x 64mm ID
PT-126676	31-177976	76mm OD x 66mm ID

Regenerex™ Augments		
Implant	**Trial**	**Description**
PT-210152	31-210152	52mm SM
PT-210252	31-210252	52mm MD
PT-210352	31-210352	52mm LG
PT-210154	31-210154	54mm SM
PT-210254	31-210254	54mm MD
PT-210354	31-210354	54mm LG
PT-210156	31-210156	56mm SM
PT-210256	31-210256	56mm MD
PT-210356	31-210356	56mm LG
PT-210158	31-210158	58mm SM
PT-210258	31-210258	58mm MD
PT-210358	31-210358	58mm LG

ArComXL® All-Poly Liners				
Implant	**Trial Cage**	**Trial Articulation**	**For Shell Size**	**Trial I.D.**
XL-222844	31-115428	31-115028	54mm	28mm
XL-222846	31-115628	31-115028	56mm	28mm
XL-223248	31-115832	31-115032	58mm	32mm
XL-223250	31-116032	31-115032	60mm	32mm
XL-223652	31-116236	31-115036	62mm	36mm
XL-223654	31-116436	31-115036	64mm	36mm
XL-223656	31-116636	31-115036	66mm	36mm
XL-223658	31-116836	31-115036	68mm	36mm
XL-223660	31-117036	31-115036	70mm	36mm
XL-223662	31-117236	31-115036	72mm	36mm
XL-223664	31-117436	31-115036	74mm	36mm
XL-223666	31-117636	31-115036	76mm	36mm

ORDERING INFORMATION

SHELL INSTRUMENTATION

Shell Impactor Plates

31-177710	Small
31-177720	Medium
31-177730	Large
31-177740	Extra Large

Shell Impactor Domes

31-177754	54mm
31-177756	56mm
31-177758	58mm
31-177760	60mm
31-177762	62mm
31-177764	64mm
31-177766	66mm
31-177768	68mm
31-177770	70mm
31-177772	72mm
31-177774	74mm
31-177776	76mm

Ratcheting Screw Driver Handle

31-424200

Torque Limiting Adaptor

31-177800

U-Joint Shaft

31-424202

Straight Ratchet Shaft

420042

Straight Magnum Handle

S313141

Straight Magnum Handle Cable Assembly

S313143

Plate Removal Tool (5/64" Hex)

S313135

Shell Trial Handle

31-177901

AUGMENT INSTRUMENTATION

Acetabular Augment Ball/Spike

124090

Augment Holder

31-177701

Augment Nail Driver Handle

31-177702

Augment Nail

31-177712	20mm
31-177713	30mm
31-177714	40mm
31-177715	50mm
31-177716	60mm

Depth Gauge

31-111114

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01-50-0926
Date: 04/06

Biomet® Regenerex™ Porous Titanium Hip Products

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet manufactures a variety of hip joint replacement prostheses. Hip joint replacement components include: acetabular shells and acetabular augments. Components are available in a variety of designs and size ranges intended for both primary and revision applications.

Materials

Acetabular Shells	Titanium Alloy
Acetabular Augments	Titanium Alloy

INDICATIONS

The porous titanium acetabular shells are indicated for cemented or non-cemented use in total hip replacement in cases of:

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.

Specific indications for compatible components (femorals, heads, liners, and screws) that can be used with Regenerex™ Hip Products are found in their individual package inserts.

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. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
2. 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.
3. 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.
4. 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.

5. 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.
6. 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.
7. **Porous titanium acetabular shells require the placement of all-polyethylene liners using acrylic bone cement.**
8. Porous titanium augments must be attached to the acetabular shells using acrylic bone cement.
9. Acetabular shells and augments should only be used with compatible FDA cleared acetabular liners, femoral components, and heads.

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.
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.

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

REFERENCES

1. Data on file at Biomet, Inc. Bench test results are not necessarily indicative of clinical performance.

2. Testing done on animal models.

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

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