PAR 5™
PROTRUSIO ACETABULAR RECONSTRUCTION SYSTEM
The obturator foramen hook can enhance long-term cup fixation and aids in maintaining the normal center of rotation.

The nine modular iliac flange options allow for screw fixation to high quality ilium host bone.

Modular, malleable, and disposable trials allow for precise determination of fit prior to final component assembly.

Commercially pure titanium hook can be crimped in the obturator foramen.

The ischial blade reduces the potential for toggling and enhances component stability.
Biomet’s PPS® titanium-alloy plasma sprayed porous coating is a “closed pore” design that potentially acts as a barrier to the migration of particulate debris and provides for exceptional rotational stability and long-term fixation.

Commercially pure titanium flange allows this malleable flange to be customized to the patient’s anatomy.

High strength titanium alloy offers rigidity and stability in the ischium.

PAR 5™ components are manufactured from titanium alloy, taking advantage of titanium’s high strength and excellent biocompatibility.
**Max-Rom™ Liner**

The Max-Rom™ liners are designed for patients with stable joints at trial reduction who require minimal additional stability. An increased chamfer allows for 125-degree range of motion.

**Hi-Wall Liner**

The hi-wall liner offers an extended polyethylene articulating surface through an arc of 160-degrees about the liner opening to enhance hip stability.

**10-Degree Liner**

The 10-degree liner adds an additional offset of 3.2mm to 5.8mm as the shell gets larger. This liner restores the placement of acetabular components which are vertically placed.

**10-Degree Hi-Wall Liner**

The 10-degree hi-wall liner combines additional posterior stability with an added offset of 3.2mm to 5.8mm to restore and stabilize acetabular components which are vertically placed.

**M²a-RingLoc™ Liner**

This design incorporates proven metal-on-metal technology with ArCom® direct compression molded polyethylene. This design fits into all Biomet® RingLoc® shells, for primary and revision indications and is offered in a standard and 10-degree face.

**+5mm Hi-Wall Liner**

The +5mm hi-wall adds 5mm of additional offset throughout the entire size range. This offset lateralizes the articulating socket into a more anatomic position for the patient with a very deep acetabulum or when additional offset is desired.

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For patients with higher expected activity levels, Biomet’s ArComXL™ polyethylene or M²a-RingLoc™ liners may be appropriate.

**ArComXL™ Highly Crosslinked Polyethylene Liners:**
- 47–64% volumetric wear reduction\(^1\)
- 30% increase in ultimate tensile strength in the longitudinal axis\(^1\)
- no measureable oxidation after accelerated aging\(^1\)

**M²a-RingLoc™ Metal-on-Metal Liners:**
- 28mm metal-on-metal construct is engineered to substantially reduce wear; design has been in clinical use since 1988
- can be used in any PAR 5” acetabular shell
- can be used in conjunction with any Biomet® femoral stem design

\(^1\) Data on file at Biomet.
**STEP 1**
After the existing acetabular component has been removed, all soft tissue and devitalized bone is removed from the acetabulum. The remaining bone is inspected to ascertain the nature and quality of the bone that will be available for support and fixation of the new component.

**STEP 2**
The hemispherical portion of the new component should rest on any remaining host bone in the superior or posterosuperior acetabulum. Various size trials should be fit to the acetabulum to ascertain the correct size.

**STEP 3**
In some cases it may be necessary to partially ream or remove protruding bone superomedially to allow better purchase, or seating of the component. The reamer should be kept “low” to position the inferior portion of the cup just above the base of the cotyloid fossa.

**STEP 4**
Once the correct size has been determined, the inferior portion of the acetabulum is exposed. This is best done with a periosteal elevator to clear the base of the cotyloid fossa. The inferior hook and the disposable superolateral trial flange are attached to the trial component and the component is then placed in the acetabular defect.

**STEP 5**
The trial for the superolateral flange is contoured to fit the ilium. The region of the ischium is also inspected to ensure that the orientation of the trial prosthesis is correct and that, if possible, the ischial blade will engage the bone. When this has been done, remove the trial implant.

The PAR 5™ System surgical technique is utilized by Kent Samuelson, M.D., and Christopher Peters, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the prosthesis in each individual patient. Biomet is not responsible for selection of the appropriate surgical technique or device to be used for an individual patient.

The PAR 5™ Acetabular System was designed in conjunction with Kent Samuelson, M.D., and Christopher Peters, M.D., both of Salt Lake City, Utah.
**STEP 6**
Referring to the trial components for proper sizing, assembly of the final implant may begin. The PAR 5™ Cup utilizes its own 2.5mm hex screws for the assembly of its parts. 
*Note: When attaching the flange to the implant, alternate the tightening of the two screws to allow for proper hole alignment.*

**STEP 7**
The disposable superolateral trial flange is removed and the actual superolateral flange implant is contoured to match the trial with the bending tool with actual flange attached to implant cup.

**STEP 8**
Bone graft is placed into all the bony defects taking care not to cover bone that will be used for weight bearing.

**STEP 9**
The component is inserted with the inferior hook first and then superiorly brought down into the acetabulum and is impacted into position, while compressing the bone graft.

**STEP 10**
Screws should now be inserted into the dome (anterosuperior or posterosuperior quadrant) of the acetabulum. The PAR 5™ Cup utilizes 6.5mm low-profile screws in the dome. The screws should provide solid fixation of the component and “lock” the PAR 5™ Cup into place by drawing the hook proximally into the bone at the base of the cotyloid fossa.

Also, consideration should be given to the direction of the screws placed in the dome of the cup to allow placement of screws through the superolateral flange. At this point, the obturator hook may be crimped, securing it to the cotyloid fossa.
STEP 11
The superolateral flange is secured to the pelvis with 6.5mm screws. As one moves from inferior to superior, the ilium becomes thinner and short screws should be used. Purchase can be improved by aiming screws posteriorly into the posterior column.

STEP 12a
Attach the appropriate size guide support to the blade guide. The selection of the guide support size should correspond to the appropriate size liner.

STEP 12b
Utilizing the blade insertion hole in the implant, place the post of the blade guide in the hole and secure the device by securing the thumb screw to the shell.

STEP 12c
With the implant held in place, the blade punch is passed through the blade guide and the cup and then removed. The ischial blade is inserted and screwed into position.

FINAL PLACEMENT
1) Blade Punch
2) Blade Guide Support (Sizes: 23–25)
3) Blade Guide
4) Hook Provisional
5) Metal Frame Shell Gauge
6) Disposable Flange Trial (Left, Right & Neutral)
7) Blade Inserter/Extractor
8) Protrusio Cage Bending Tool
9) Ratchet Handle
10) 2.5mm Straight Hex Shaft
11) 2.5mm Swivel Hex Shaft

**LINER SIZING REFERENCE CHART**

<table>
<thead>
<tr>
<th>Shell Diameter</th>
<th>Liner Size</th>
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<tbody>
<tr>
<td>56mm</td>
<td>23</td>
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<tr>
<td>60mm</td>
<td>23</td>
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<tr>
<td>64mm</td>
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<td>68mm</td>
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<td>72mm</td>
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DESCRIPTION
Biomet manufactures acetabular products used in primary and secondary revision applications. These products include titanium alloy cups, and modular products that utilize various elements for fixation such as flanges, hooks, and blades. Par 5° acetabular components are intended for use in cemented or non-cemented applications.

Components are available in a variety of designs and size ranges intended for revision applications to address bone defects.

Materials
- Acetabular Shells: Titanium Alloy
- Acetabular Liners: Ultra-High Molecular Weight Polyethylene (UHMWPE)
- Screws: Titanium Alloy
- Blades: Titanium Alloy
- Flanges and Hooks: Commerially Pure Titanium
- Coating: Calcium Phosphate

INDICATIONS
Par 5° Shell Acetabular components are indicated for use 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 chrothoantric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

Shell components are to be used with Biomet® RingLoc® Acetabular Liners.

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

CONTRAINDICATIONS
Absolute contraindications include: infection, sepsis, and osteomyelitis.

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

WARNINGS
Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate pressfit cleaning (removal of surgical debris) can lead to excessive wear. The Hydroxyapatite Coating on the prosthesis device should only be handled while wearing clean surgical gloves. Improper preoperative or intraoperative implant handing or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

1. Hinges and hooks should not be bent in the same location more than once. Bending of flanges and/or hooks can weaken the metal.
2. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
3. 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.
4. 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.
5. Screws are to be fully seated to assure stable fixation. Blade and hook components must be fully seated and secure to prevent premature failure.
6. Care is to be taken to assure complete support of all parts of the device when 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.

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.

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 construction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight 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.

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Date: 01/06

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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. Intraoperative or postoperative bone fracture and/or postoperative pain.

15. Failure of the device or procedure in the presence of pelvic discontinuity.

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.

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