Biomet Patient-Matched (PMI) Joint Replacement Implants

ATTENTION OPERATING SURGEON

DESCRIPTION
PMI Joint Replacement Implants are intended for patients with conditions that, in the surgeon’s opinion, cannot be satisfactorily treated using standard line implants. These patient matched components utilize Computerized Tomography (CT) scans to create flanged acetabular components, CT Hips (femoral components), and Performa Patella Femoral components.

MATERIALS
PMI Joint Replacement Implants are made from a variety of materials, depending upon patient need and/or implant design specifications. Possible materials used may include:
- Titanium Alloy
- Cobalt Chromium Alloy
- Hydroxypatite (HA)

INDICATIONS

Flanged Acetabular Indications for Cemented Application
The Patient Matched Flanged Acetabular Component is indicated for use in patient requiring reconstruction of the hip joint due to disease, deformity or trauma. The device is intended for cemented application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints. The device is a single use implant. The device is to be used in conjunction with Biomet’s Ringloc Acetabular Liners. The device may be used with any commercially available femoral component.

Flanged Acetabular Indications for Uncemented Application
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 treatments or devices have failed.

HA Coated Flanged Acetabular Indications
The Patient Matched Flanged Acetabular Component is indicated for use in patient requiring reconstruction of the hip joint due to disease, deformity or trauma. The device is intended for cementless application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints. The device is a single use implant. The device is to be used in conjunction with Biomet’s Ringloc Acetabular Liners. The device may be used with any commercially available femoral component.

HA CT Hip Indications
Non-Cemented use for skeletally mature patients undergoing primary hip replacement surgery as a result of non-inflammatory degenerative joint disease.

CT Hip Indications
Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
   1. Rheumatoid arthritis.
   2. Correction of functional deformity.

3. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
4. Revision procedures where other treatments or devices have failed.

Performa Patella Femoral
1. Patients with osteoarthritis limited to the distal femur and patella
2. Patients with a history of patellar dislocation or patellar fracture
3. Those patients with failed previous surgery (arthroscopy, tubial tubercle elevation, lateral release, etc.) where pain, deformity or dysfunction persists.

The device is a single use implant intended to be implanted with bone cement.

CONTRAINDICATIONS
Infection, sepsis, and osteomyelitis are absolute contraindications.

CT Hip Contraindications
Infection, sepsis, and osteomyelitis are absolute contraindications.

Relative contraindications include: 1) uncooperative patients or patients with neurologic disorders who are incapable of following instructions, 2) osteoporosis, 3) metabolic disorder which may impair bone formation, 4) osteomalacia, and 5) distant foci of infections which may spread to the implant site.

Flanged Acetabular for Cemented Indications and Patient Matched Trochlea Contraindications
Infection, sepsis, and osteomyelitis are absolute contraindications.

Relative contraindications include: 1) uncooperative patients or patients with neurologic disorders who are incapable of following instructions, 2) osteoporosis, 3) metabolic disorder which may impair bone formation, 4) osteomalacia, and 5) distant foci of infections (which may cause hematogenous spread to the implant site).

Flanged Acetabular for Uncemented Use , HA Flanged Acetabular, HA CT Hip 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 disorder which may impair bone formation, 4) osteomalacia, and 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 and a subsequent reduction in the service life of the prosthetic implant. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclusion removal (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 implant, instruments, and surgical procedure prior to performing surgery. For further information, contact Biomet.

Accepted practices should be followed meticulously in postoperative care. The patient must be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight and obesity have been implicated in premature failure of certain implants by contributing to loosening, fracture, dislocation, subluxation and/or wear. The patient is to be cautioned to govern activities accordingly, protecting the replaced joint from unreasonable stresses.

Use clean gloves when handling implants. The Hydroxypatite coating on the prosthetic device should only be handled while wearing surgical gloves. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissue has lower adhesion strength to cement than implants handled with clean gloves.
1. Use Biomet femoral and modular head component with appropriate matching “Type I Taper”, “Type II Taper”, “12/14 Taper”.
2. Firmly seat modular head components to minimize 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 avoid stable fixation and to minimize interference with the acetabular line component.
4. Prior to seating the liner into the shell component, all surgical debrises (tissue fragments, etc.) must be removed from the interior of the shell component, as debrises 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 damage bone structures (blood vessels, etc.) 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 specialized 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 minimize stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debrises, and other surgical debrises from the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

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 in advance of surgery, and to follow the instructions of the treating physician, including follow-up visits. The patient is to be warned that the device does not replace normal healthy bone, and that the implant cannot be expected to withstand the activity levels of normal healthy bone, and that the implant can break or be damaged as a result of strenuous activity or trauma.

Patient selection factors that should be considered include: 1) need to obtain pain relief and improve function, 2) ability of the patient to follow instructions, and 3) a good nutritional state of the patient.

Do not reuse implants. While an implant may appear undamaged, previous stress may create imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, stressed may create imperfections that would reduce

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

POSSIBLE ADVERSE EFFECTS

1. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage occurs more frequently, possibly as the result of surgical trauma.
2. Material sensitive 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 debrises 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.
3. Early or late postoperative infection and/or allergic reaction.
4. Implant 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 from previous surgery, bone resorption, or while inserting the device.
10. Implants can loosen or migrate due to trauma or loss of fixation.
11. Infection can lead to failure of the joint replacement.
12. While rare, fatigue fracture of the implant can occur as a result of strenuous activity, malalignment, or trauma.

Fracture of bone at the implantation site can occur while press-fitting (seating) the implant component into the prepared site.

Intraoperative and early postoperative complications can include: 1) bone perforation or fracture, 2) bone fracture can occur while seating the device, 3) damage to blood vessels, 4) temporary or permanent nerve damage resulting in pain or numbness of the affected limb, 5) undesirable shortening of the limb, 6) traumatic arthrodesis of other limb joints from intraoperative positioning of the extremity, 7) cardiovascular disorders including thrombosis, pulmonary embolism or heart attack, 8) hematoma, 9) delayed wound healing, and/or 10) infection.

Late postoperative complications can include: 1) bone fracture due to trauma or excessive loading, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, or bone resorption, 2) periartricular calcification or ossification, with or without impediment to joint mobility, 3) loosening or migration due to malalignment of the components or loss of fixation, and/or 4) bone resorption which may contribute to deteriorating fixation and loosening.
STERILITY
Prosthetic components are sterilized by exposure to a minimum of 25 kGy of gamma radiation. Metallic components may be resterilized using appropriate procedures for autoclaving. Single Use Only. Do Not Reuse. Do not re sterilize UHMW polyethylene components. Do not use any component from an opened or damaged package. Do not use past 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 574-372-3968.

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CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

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Symbol Legend

Manufacturer
Date of manufacture
Do not reuse
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Caution, see instructions for use
Sterilized using ethylene oxide
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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
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