

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

01-50-0981

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**Warnings and Precautions for 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 design characteristics can place limitations on the size and/or strength of the implant and as such may possess unknown or unforeseeable risks.

WARNING: The patient is to be advised of these limitations and warned that use of the device may involve unknown or unforeseeable risks. The surgeon must be familiar with the implant, its design features, method of application, instruments, and surgical procedure prior to performing surgery. In all cases sound orthopedic practices are to be followed, and the surgeon's selection of the type of device and its design features must be appropriate for treatment.

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
- Stainless Steel
- Ultra-high Molecular Weight Polyethylene (UHMWPE)
- ArComXL (highly crosslinked UHMWPE)
- E-Poly (highly cross-linked UHMWPE and α -tocopherol)
- Polyetheretherketone (PEEK)
- Tantalum
- CP Titanium
- Hydroxyapatite

INDICATIONS

The indications for use of PMI Joint Replacement Implants include:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Revision procedures where other treatments or devices have failed.
5. Treatment in conjunction with tumor resection.

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).

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 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 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.

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. 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, placed in a different patient. PMI devices are designed specifically for a named patient and must not be used to treat any other patient.

Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

PRECAUTIONS

PMI Joint Replacement Implants are designed from patient data such as radiograph (X-ray), computed tomography (CT), or magnetic resonance imaging (MRI). Over time, a patient's anatomy can change. If a significant amount of time has elapsed from the time of collection of the patient data (date of scan) to the time of surgery utilizing a PMI implant, the implant may not fit the patient's anatomy correctly.

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, incorrect 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 that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should be used only for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

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 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.

3. Early or late postoperative infection and/or allergic reaction.
4. Dislocation and subluxation of implant components have been reported resulting from improper positioning of implant components. Muscle and fibrous tissue laxity can also contribute to these conditions.
5. Implants can loosen or migrate due to trauma or loss of fixation.
6. Infection can lead to failure of the joint replacement.
7. While rare, fatigue fracture of the implant can occur as a result of strenuous activity, malalignment, or trauma.
8. 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 arthrosis 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) periarticular 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 resterilize 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.

Symbol Legend	
	Manufacturer
	Date of manufacture
	Do not reuse
	Caution, see instructions for use
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using steam or dry heat
	Use by date
	WEEE device
	Catalogue number
	Batch code
	Flammable
	Authorized representative in the European Community