



Precautionary Statement (01-50-0904)

Biomet Orthopedics, Inc.

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Date: 07/08

Maestro™ Wrist Joint Replacement System

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet manufactures wrist joint replacement prostheses intended for primary and revision joint arthroplasty for use in cemented applications. Wrist joint replacement components include: multiple piece radial and carpal components, and screws.

Materials:

Radial Stems	Titanium Alloy
Radial Bodies	Cobalt Alloy or CoCr/UHMWPE
Carpal Heads	Cobalt Alloy or CoCr/UHMWPE
Carpal Plates	Cobalt Alloy
Capitate Stems	Titanium Alloy
Carpal_Screws	Titanium Alloy
Surface Coating	Titanium Alloy

INDICATIONS

Total Wrist Indications

The Maestro™ Total Wrist and Maestro™ Wrist Fracture Replacement systems are indicated for use as a replacement of wrist joints disabled by pain, deformity and/or limited motion caused by:

1. Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Scapholunate Advanced Collapse (SLAC) and other functional deformities.
5. Trauma, including fractures of the distal radius and/or carpal bones.

Carpal Hemiarthroplasty Indications

The Maestro™ Carpal Hemiarthroplasty is indicated for use as a replacement of wrist joints disabled by pain, deformity and/or limited motion caused by:

1. Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Scapholunate Advanced Collapse (SLAC) and other functional deformities.

5. Trauma, including fractures of the carpal bones.

The radial and carpal components are intended to be implanted with bone cement.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patients 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/or 7) absent or insufficient wrist extensor tendons.

WARNINGS

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 activity levels, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

1. 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.
2. 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.
3. Thoroughly clean and dry connecting segments prior to attachment of components to avoid improper seating. 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.
4. Do not modify implants.
5. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.
6. Properly align and securely assemble connecting components. Failure to properly align and completely seat the components together can lead to disassociation. Thoroughly clean and dry all connections prior to attachment of modular components to avoid improper seating.
7. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations that 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 with joint replacement implants.
8. 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.
9. 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 limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred.

10. Excessive activity, trauma and excessive load bearing have been implicated with premature failure of implants 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.
11. 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.
12. Do not use poly carpal head with any other radial implant other than the Maestro™ Radial Fracture implant.

Wrist joint replacement prostheses have not received FDA clearance for non-cemented application (USA).

Maestro™ Wrist implants have not received FDA clearance for radial-hemiarthroplasty indications.

PRECAUTIONS

1. Specialized instruments are designed for Biomet® joint replacement systems to aid in the proper 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 that 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.
2. 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.
3. Patient must avoid placing excessive loads on the implant.
4. Patient must avoid lifting more than 5 lbs with the operated arm after surgery.
5. Patient must avoid putting full body weight on the operated arm when rising from a seated position.
6. Patient must avoid sudden or strenuous pushing and/or pulling activities after surgery, as these can produce excessive stress on the operated arm.
7. Patients must avoid full wrist flexion or extension under load bearing conditions.
8. Pay careful attention to possible soft tissue irritation as a result of the volar flange (Maestro™ Radial Fracture implant only).

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. Nerve injury is a concern in all joint replacement procedures.
5. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive activity.
6. Periarticular calcification or ossification, with or without impediment of joint mobility.
7. Inadequate range of motion due to improper selection or positioning of components.

8. Undesirable shortening or lengthening of limb.
9. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
10. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive load bearing.
11. Fretting and crevice corrosion can occur at interfaces between components.
12. Wear and/or deformation of articulating surfaces.
13. Intraoperative or postoperative bone fracture and/or postoperative 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 past expiration date.

Caution: Federal law (USA) restricts this device to sale, distribution, or use 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, FAX: 574-372-3968.

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