Custom / Specialty Orthopedic Products

151809-00

The following languages are included in this packet:

English (en)

For additional languages, visit our website www.ortho.microport.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.

MicroPort Orthopedics Inc.
5677 Airline Rd
Arlington, TN 38002
U.S.A.

℞ ONLY

April 2015
Printed in U.S.A.

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

Custom / Specialty Orthopedic Products

(151809-00)

As a custom-made product, the enclosed prosthesis has been designed according to the operating surgeon's prescription and approval.

Through the advancement of the field of joint replacement/fixation prostheses, surgeons have been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While custom prostheses can also be largely successful in attaining these goals, there can be no guarantee of such. It must be recognized that prostheses are manufactured from metal and plastic materials, and, therefore, cannot be expected to withstand the activity levels and loads as would normal healthy bone. In addition, the system will not be as strong, reliable, or durable as natural human tissue. Finally, given the unique nature of this custom-made prosthesis, the patient should be aware that it has not been subject to any testing.

In using joint replacement/fixation prostheses, the surgeon should be aware of the following:

A. **The correct selection of the prosthesis is extremely important**. The potential for success in joint replacement/fixation surgery is increased by selection of the proper size, shape, and the surgeon's design parameters of the prosthesis. Orthopedic prostheses require careful seating and adequate bone support. Smaller sized implants are intended for patients of slight weight and low activity level. Such components could be inappropriate for other patients. Surgeons are encouraged to use their best medical judgement when choosing the proper implant size regardless of the endosteal area of the bone.

B. **In selecting patients for joint replacement/fixation, the following factors can be critical to the eventual success of the procedure**:

1. **Patient's weight**. An overweight or obese patient can produce loads on a prosthesis which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned and a small size prosthesis must be used.
2. **Patient's occupation or activity**. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
3. **Condition of senility, mental illness, or alcoholism**. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
4. **Foreign body sensitivity**. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

Description

This custom prosthesis is a non-standard product manufactured to meet the specific needs and requirements for an individual patient and/or the request of a specific surgeon.

Indications

Custom/specialty prostheses are typically used in revision cases where failed or loosened prostheses from previous surgery are being replaced.

Another typical reason for use is replacement of a section of bone due to a pathological fracture, non-union, bone tumor and/or any other serious bone defect. These prostheses are ordered to meet the specific requirements of the patient and surgeon when they cannot be met through the use of a commercially available product.

Contraindications

Absolute contraindications include:

1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4) skeletally immature patients; and
5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the affected area which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

1) uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2) marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
3) metabolic disorders which may impair bone formation;
4) osteomalacia; and
5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

Warnings

Improper selection, placement, positioning, and fixation of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component. The surgeon must be thoroughly familiar with the implant, instruments, and intended surgical procedure prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Medical procedures for optimal utilization of the prosthesis should be determined by the physician. However, the physician is advised that there is recent evidence that the potential for deep sepsis following joint replacement/fixation surgery may be reduced by:

1. Consistent use of prophylactic antibiotics;
2. Utilizing a laminar flow clean air system;
3. Having all operating room personnel, including observers, properly attired;
4. Protecting instruments from airborne contamination; and
5. Impermeable draping;

Metal Components. Some of the alloys used to produce orthopedic prostheses may contain some elements that may be carcinogenic in tissue cultures or intact organisms. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic to actual prosthetic recipients. Studies conducted to date to evaluate these questions have not produced convincing evidence of such phenomenon.

Materials. Joint replacement/fixation components are manufactured from a variety of materials which include cobalt-chromium-molybdenum alloy, titanium alloy, unalloyed titanium, stainless steel, ceramic, hydroxylapatite, polymethylmethacrylate (PMMA), and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM standards.

Prosthetic Components
Do not mix components of different prosthetic systems or from different manufacturers. Be aware that mixing certain sizes of the same prosthetic system may be inadvisable. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of modular components which could compromise the locking action of the components. Surgical debris must be cleaned from components before assembly since debris may inhibit proper fit and interfere with the locking mechanisms of modular components, which may lead to early failure of the procedure.

Alignment of Components
Care should be taken to restore proper joint alignment and balance ligamentous tension. Misalignment of the joint can cause excessive wear, loosening of the prosthesis, and pain leading to premature revision of one or more of the prosthetic components.

Press-Fit Application (Hip Prostheses Only). Tight fixation at the time of surgery is critical to the success of the procedure. The femoral component stem must press fit into the femur, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur can occur during seating of the prosthesis. Bone stock must be adequate to support the device.

Cemented Application. Care is to be taken to assure complete support of all parts of the device imbedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Complete cleaning prior to closure (complete removal of bone chips, bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.

Fixation Screws. Fixation screws, when used, should be fully seated to assure stable fixation and to avoid interference with the proper seating of components. Use only screws recommended by the manufacturer of the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals. Be careful to place screws in the proper position and angle.

Precautions

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 activity and trauma have been associated with failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

The patient is to be cautioned to limit activities and protect the prosthesis from unreasonable stresses, and follow the instructions of the physician with respect to follow-up care and treatment.

The patient is to be warned of surgical risks, and made aware of possible adverse effects. The patient is to be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity, trauma, or normal use, and has a finite expected service life and may need to be replaced at some time in the future.

Adverse Effects

1. Wear of polyethylene articulating surfaces of prosthetic components has been reported. Higher rates of wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.

2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components such as a consequence of foreign-body reaction to particulate matter. Particulate is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particulate can also be generated by third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. See **Important Physician Information** section for more information.

3. Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts.

4. Peripheral neuropathies have been reported following joint replacement/fixation surgery. Subclinical nerve damage has been reported, and may occur as the result of surgical trauma.

5. Dislocation and subluxation of prosthetic components can result from improper positioning of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.

6. Prosthetic components can loosen or migrate due to trauma or loss of fixation.

7. Infection can lead to failure of the joint replacement.

8. While rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.

9. Bone fracture can occur while seating a prosthetic component.

Intraoperative and early postoperative complications can include:

1) perforation or fracture;
2) damage to blood vessels;
3) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
4) undesirable shortening or lengthening of the limb;
5) traumatic arthrosis from intraoperative positioning of the extremity;
6) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction.
7) hematoma;
8) delayed would healing; and
9) infection.

Late postoperative complications can include:

1) avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening;
2) non-union due to inadequate reattachment and or early weight bearing;
3) aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;
4) fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
5) periarticular calcification or ossification, with or without impediment to joint mobility;
6) inadequate range of motion due to improper selection or positioning of components, impingement, or periarticular calcification.

Important Physician Information.

Bone resorption is a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to implant loosening and failure. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by cement, metal, ultra-high molecular-weight polyethylene (UHMWPE), and ceramic. Regarding the etiology, it has been hypothesized that particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution, and amount of particulate debris (rate of debris generation). The phagocytic action results in the release of cytokines and intercellular mediators (IL-1, 2, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis for the causes of this phenomenon and potential ways to reduce its occurrence.

Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

Handling and Sterilization

Unless supplied non-sterile, this product has been sterilized and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using accepted sterile technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product. This is particularly important in handling porous coated prostheses. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials.

This product is for single use only. A prosthesis should never be reused. While it may appear undamaged, microscopic imperfections may exist which would reduce the service life of the prosthesis.

A prosthesis should never be resterilized or reused after contact with body tissues or fluids, but rather should be discarded.

Warning: Disassemble components prior to sterilization/resterilization.

Warning: You must **NEVER** steam sterilize/resterilize ceramic, plastic, and/or metal/plastic components. If sterilization/resterilization of the metal component(s) is required, proceed accordingly.

The following sterilization recommendation has been developed using specific equipment for a SAL of 10^{-6} and may vary depending on processing conditions, wrapping materials, or equipment. The cycle and conditions must be demonstrated to produce sterility in your environment.

1. Disassemble components prior to sterilization.

2. Wrap the component in central supply room (CSR) type non-woven medical grade wrapping material or place in a sealed sterilization pouch. If using a 270°F(132°C) pulsing vacuum cycle, the component may also be placed on a standard mesh sterilization tray.
3. Autoclave according to the following parameters:

Method	Cycle	Temperature	Exposure
Steam	Gravity	250°F(121°C)	30 minutes
Steam	Pulsing Vacuum	270°F(132°C)	5 minutes

After sterilization, remove the component from its packaging or the sterilization tray using accepted sterile technique with powder-free gloves. Ensure that the component is at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.