Indications for Use

Tri-plus® Cross-link/Acetabular Liner

Manufacturer
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DESCRIPTION

The Tri-plus® Cross-link Acetabular Liner is manufactured from ultra-high molecular weight polyethylene (UHMWPE) which has been crosslinked by radiation, and is referred to as extensively cross-linked polyethylene (EXPE). The Tri-plus® Acetabular liner is manufactured from ultra-high molecular weight polyethylene (UHMWPE) which was manufactured by a compression molding process and is referred to as compression molded polyethylene (CMPE, ASTM F-648). The Tri-plus® Cross-link and the Tri-plus® Acetabular Liners are available in both neutral and hooded designs. The Tri-plus® Cross-link liner includes inside diameter options of 22, 28, 32 and 36mm. The Tri-plus® Acetabluar Liner includes inside diameter options of 22, 28 and 32mm. The outside diameter options available range in size from 40mm-70mm in 2mm increments. All of these components are provided in individually sterilized packaging.

Tri-plus® Cross-link/Acetabular Liner system may be used in conjunction with the Quadra®-S, CoCr head hip prosthesis system and MectaCer BIOLOX® Forte femoral heads manufactured by Medacta International.

INDICATIONS

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

CONTRAINDICATIONS

1. Any joint with active or suspected local or systemic infection.
2. Any pathological condition of the joint that would preclude rigid fixation, appropriate range of motion or adequate support or fixation of the component.
3. Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustifiable.
4. Certain systemic or metabolic bone conditions.
5. Skeletal immaturity.
6. Poor bone quality that cannot provide adequate support or fixation of the implant.
7. Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant.
8. Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
9. Pathological conditions, neuromuscular disorders or mental conditions whereby the risks associated with these conditions outweigh the benefits to be derived.

WARNINGS AND PRECAUTIONS

Before using any implant the surgeon should be familiar with the fundamentals of hip arthroplasty as well as the

limitations of the device. Instruction should be given to the patient on the limitations of the prosthesis and how to modify their lifestyle accordingly. Proper selection of the implant is extremely important as the potential for success in total joint replacement is increased by the selection of the proper size implant. Total joint replacement requires careful seating and adequate bone support and should be restricted to limited functional stress. Extreme care should be taken by the surgeon and the O.R. staff to protect the component surface from being marred as a result of contact with metal or any abrasive objects.

The Tri-plus® Cross-link and Tri-plus® Acetabular Liners should not be used with other systems and vice versa, unless specifically designated and labeled for such use. This device is intended for use with other components, trials, and instruments manufactured by Ortho Development. Different specifications and dimensional incompatibilities among the various systems may cause premature failure.

The Tri-plus® Cross-link and Tri-plus® Acetabular liners are sold sterile. Do not implant this or any device that has been used or that has evidence of damage or tampering. Take extreme care to protect the device from coming in contact with any hard or abrasive surfaces especially in polished bearing or machined taper areas. The machined taper surface of the femoral trunion/neck must be dry and free from any tissue or fluid at the time of assembly with the femoral head to ensure proper seating of the implant. The femoral head must be properly impacted to prevent neck length discrepancy, disassociation, or dislocation. Never tamper with the implant. Do not bend or contour the implant, as this may reduce the fatigue strength and may cause immediate or eventual failure of the implant.

The following factors may tend to impose risk of implant failure:
1. Obesity.
2. Heavy labor.
3. Active sports participation.
4. History of falls.
5. Drug or alcohol addiction and/or abuse.
6. Foreign body sensitivity.
7. Severe deformities, congenital dislocation.
8. Local tumors of the bone.
9. Systemic and metabolic bone disorders.
10. History of infectious disease.

ADVERSE EFFECTS
All prosthetic replacements have the potential for adverse effects including but not limited to:

Intraoperative:
1. Acetabular/Femoral perforation.
2. Femoral fracture during bone preparation or impaction.
3. Damage to blood vessels or nerves.
4. Death (secondary to cardiac arrest).
5. Subluxation or dislocation of the implant due to selection and/or positioning of components and/or muscle and fibrous tissue laxity.
6. Undesirable shortening or lengthening of the affected extremity.
7. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.
8. Inadequate abutment in the direction of the resultant joint force.

Early Postoperative
1. Cardiovascular disorders including venous thrombosis, pulmonary embolism, pneumonia, atelectasis, cerebrovascular accident, myocardial infarction, and death.
2. Hematoma and delayed wound healing.
3. Systemic or wound infection.
4. Sensitivity or allergic reactions to the materials used to manufacture the component.
Late Postoperative
1. Trochanteric avulsion from excessive muscular tension or early weight bearing and inadvertent intraoperative

weakening.
2. Aggravated problems in the knee and ankle joints of the affected or contralateral extremities caused by leg length discrepancy.
3. Femoral or acetabular fracture by trauma or excessive loading, bone defects from previous surgery or reaming, and bone resorption.
4. Failure due to implant fracture.
5. Tissue reactions, allergic reactions, and loosening caused by metallic corrosion or the accumulation of wear debris from the acetabular socket or loose cement particles.

PACKAGING AND STERILITY
All implants have been sterilized by a minimum of 25kGy gamma irradiation at a sterility assurance level of 10^{-6}. Sterile product packaging should be inspected for flaws before and after opening. In the presence of a flaw or if implant sterility has been compromised the product must be considered non-sterile and should not be implanted. Resterilization of the implant is not recommended.

INSTRUMENT STERILITY
All instruments should be thoroughly cleaned prior to sterilization. The following Steam Sterilization Cycles must be followed in order to ensure sterility:

Gravity Cycle: 30 minutes at 132° C (270° F), 105 minutes dry time.
Prevacuum Cycle: 4 minutes at 132° C (270° F), 75 minutes dry time.

PRODUCT HANDLING
Implants should always be stored unopened in their respective protective packages. Prior to use, inspect packaging for damage which may compromise sterility. When removing the implant from its packaging, the relevant aseptic techniques must be observed. Protect the prosthesis from contact with objects which may damage the surface finish. Inspect each implant prior to use for visual damage. Do not implant this or any device that has been used, even if it appears undamaged.

PRODUCT COMPLAINTS
Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to Ortho Development® Corporation. If any of the implants or instruments "malfunction" (i.e., do not meet any of their performance specifications or does not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, Ortho Development® Corporation should be notified immediately by phone, fax or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant's name and address, and the nature of the complaint.

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

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