

Biomet Orthopedics
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Revision C

Date: 2011-11



Taperloc™ Complete Hip Joint Replacement Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet® Taperloc™ Complete stems are porous coated femoral stems intended for uncemented biological fixation. They are offered in various sizes and offsets, as well as standard full-length and shortened Microplasty stem lengths. BoneMaster™ HA coated stems, the only available HA coating for Taperloc™ Complete stems, are for sale outside the United States only. The Taperloc™ Complete hip stems can be used for either total or hemi hip arthroplasty.

MATERIALS

Femoral Stems	Titanium Alloy
Porous Coating	Titanium Alloy
Hydroxyapatite (HA) Coating (BoneMaster™ HA coated)	Calcium Phosphate

NOTE: The BoneMaster™ HA coated and Taperloc™ Complete 12/14 Taper femoral stems are not available for sale in the USA.

INDICATIONS

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 by other techniques.
5. Revision procedures where other treatment or devices have failed.

Porous coated components are intended for uncemented biological fixation.

COMPATIBLE COMPONENTS

Specific indications, contraindications, warnings, precautions and possible adverse device effects for compatible components that can be used with the Taperloc™ Complete hip stems are found in their individual package inserts.

Taperloc™ Complete hip stems are compatible with the following Biomet® components:

- a) All Biomet® Type I modular heads and Biomet® 12/14 Taper modular heads except the Zirconia ceramic modular heads. (The C2a-Taper™ / Biolox™ Forte head/liner combinations and Taperloc™ Complete 12/14 Taper femoral stems are not available for sale in the USA).
- b) All Biomet® acetabular shells, screws and augments including metal-on-metal and constrained acetabular shells. If used with a metal-on-metal configuration, please consult the appropriate product insert for additional information, contraindications, and warnings.
- c) All Biomet® acetabular liners including metal-on-metal and constrained acetabular liners, excluding the C2a-Taper™ / Biolox™ Forte head/liner combinations in the USA.
- d) The Taperloc™ Complete hip stems are not compatible with femoral heads that have greater offsets than +12mm.

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 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 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 which may lead to subsequent reduction in the service life of the prosthetic components. 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 implants and instruments, prior to performing surgery.

1. Use Biomet® femoral and modular head component with appropriate matching “Type I Taper”, “Type II Taper”, or “12/14 Taper”.
2. Firmly seat modular head components to prevent 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 to avoid interference with the acetabular liner component.
4. In any instance where a liner engages the RingLoc™ locking ring and the liner is subsequently removed or replaced, the RingLoc™ locking ring should be replaced with a new ring.
5. Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
6. 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 cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
7. 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 specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
8. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which 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.
9. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

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.

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 limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive unusual and/or awkward movement and/or activity, trauma, weight gain, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation,

subluxation 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. 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.

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

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.

PRECAUTIONS

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, 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, which 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.

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

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. 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.
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. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, malposition, bone resorption, excessive weight, or excessive unusual and/or awkward movement and/or 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 malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. 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, strenuous activity, malalignment, trauma, non-union, or excessive weight.

10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. Postoperative bone fracture and pain.

MRI Information

This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Single Use Only. Do not use any component from an opened or damaged package. Do not use implants after 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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BioloX™ is a trademark of CeramTec AG.

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
	Caution
	Sterilized using Ethylene Oxide
	Sterilized using Irradiation
	Sterile
	Sterilized using Aseptic Processing Techniques

STERILE



Sterilized using Steam or Dry Heat



Use By



WEEE Device

REF

Catalogue Number

LOT

Batch Code



FLAMMABLE

Flammable

EC

REP

Authorized Representative in the European Community