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Revision F
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Freedom Constrained Liner System

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet® *Freedom* Constrained Liner System is intended for use only in special situations where the patient has a high risk of dislocation due to a previous history of dislocation, severe joint laxity, and/or palsy of surrounding musculature. With the exception of the All-Poly liners, the Biomet® *Freedom* Constrained Liner w/ locking ring will mate to any compatible Biomet® Ringloc shell. The All-Poly liners are cemented directly into a Max-Ti Cage, Mallory/Head Cage, Recovery Cage, or directly into the acetabulum. Biomet® *Freedom* Constrained Liners are only compatible with 36mm *Freedom* Modular Heads with a -6, -3, Standard, +3, +6, or +9 neck.

MATERIALS

Liner	ArCom Ultra-High Molecular Weight Polyethylene (UHMWPE), ASTM F-648
Locking Ring	Titanium 6Al-4V ELI Alloy, ASTM F-136
Modular Head	Co-Cr-Mo, ASTM F-1537

INDICATIONS

The Biomet® *Freedom* Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability, and for whom all other options to constrained acetabular components have been considered.

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 levels, 3) a good nutritional state of the patient, and 4) the patient should be skeletally mature.

CONTRAINDICATIONS

1. Bone or musculature compromised by disease, infection, or prior implantation that cannot provide adequate support or fixation for the prosthesis.
2. Any active or suspected infection in or about the hip.
3. Skeletal immaturity.

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, including the retaining ring. Please see the Biomet® *Freedom* Constrained Liner's surgical technique for the correct positioning and attachment of the constrained liner. 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. Closed reduction of a dislocation of a constrained hip is not possible. Patients should be made aware that treatment of device dislocation would require additional surgery.

1. Use Biomet® femoral and *Freedom* modular head component with appropriate matching "Type I Taper" or "12/14 Taper".
2. The Biomet® *Freedom* Constrained Liner System is to be used only with Biomet® Femoral, Acetabular Shell, and Femoral *Freedom* Head components. See Biomet® Hip Joint Replacement Prosthesis package insert for indications, contraindications, warnings, and precautions concerning use of these components.
3. 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.

4. Care should be taken to ensure proper head orientation with the etched line being placed in the most superior position. Incorrect head orientation can increase the likelihood of disassociation from the liner during normal activities.
5. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
6. 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.
7. The Biomet® *Freedom* Constrained Liner System requires accurate anatomical alignment and careful positioning to prevent impingement with the femoral component.
8. Retaining ring failure and/or disassociation, which may be due to impingement, fatigue, and/or wear, increases the probability of dislocation.
9. Failure or migration of the retaining ring may require additional surgery.
10. The Biomet® *Freedom* Constrained Liner System operates only with Biomet® 36mm *Freedom* modular head components with +9, +6, +3, standard, -3, and -6mm neck lengths. For further information contact Biomet.
11. Anatomical alignment is critical to the success of the procedure. Failure to achieve proper anatomical alignment may result in impingement, reduction in the range of motion and excessive wear, or failure of the retaining ring.
12. The femoral head can disassociate from the constrained liner if the head is moved into the plane of insertion while pulling stress is being placed on the extremity.
13. 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.
14. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

While the Biomet® *Freedom* Constrained Liner System is intended for use in treating chronic dislocation, the device will not correct joint laxity, palsy, malalignment, or other causes of dislocation. If problems causing dislocation are not corrected, undue stress will be placed upon the device, which will result in excess wear of the implants including the retaining ring and may cause failure.

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.

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 with implants that have been, even momentarily, placed in a different 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.

PRECAUTIONS

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic component. 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 subjected to wear with normal usage. Instruments that have experienced 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.

In order to minimize the risks of dislocation and loosening of the shell, surgeons should consider providing immediate resistance to tensile forces on the metallic shell (at either the shell-acetabular bone interface or the shell-bone cement interface) through the use of bone screw, spikes, screw threads, fins, or other bone fixation devices. This should be considered when using metallic shells for either biologic fixation or cemented fixation. The surgeon should also consider the component malposition, component placement, alignment, and effect on

range of motion when using extended liners. Failure to consider any of these can lead to failure of the device, including the retaining ring.

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 dated March 2010, titled "Advice from the CSD Expert Advisory Group on the biological effects of metal wear debris generated from hip implants," 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/or 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, bone resorption, and/or excessive 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 and improper positioning. 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. Retaining ring failure or migration which may be due to impingement, fatigue, excessive stress, and/or wear increases the risk of dislocation, and therefore may require additional surgery.
12. Wear and/or deformation of articulating surfaces.
13. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
14. 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.
15. Intraoperative or postoperative bone fracture and/or postoperative pain.

INSTRUCTIONS FOR UTILIZATION AND IMPLANTATION

1. Before clinical use, the surgeon should be familiar with all aspects of the surgical procedure and the limitations of the device, including the orientation required for the circumferential flat on the modular head to be inserted into the liner.
2. Prior to seating the *Freedom* Constrained Modular Head onto the femoral taper, make sure the etched line on the modular head is placed in the superior position.
3. If an uncemented acetabular shell is utilized, bone screws should be used to supplement fixation.
4. Bearing areas must be clean and free from debris prior to assembly.
5. Trial components should be used for preliminary size determination, trial reduction, and range of motion evaluation. A final trial reduction can be performed with the constrained liner in place. A complete intraoperative range of motion must be obtained with no visual or tactile obstructions.
6. The interior surface of the liner and the surface of the modular head should be free of excessive moisture to prevent a moisture seal forming between the components during insertion. A moisture seal could make implantation difficult.
7. The surgeon may obtain additional information by reviewing the surgical technique for the particular Biomet hip replacement prosthesis being utilized.

PATIENT COUNSELING INFORMATION

In addition to the patient related information contained in the Warnings and Possible Adverse Effects sections, the following information should be conveyed to the patient.

1. The prosthesis will not restore function to the level expected with a normal healthy joint, and the patient should be instructed as to the limitations of the device. The range of motion achievable with a constrained liner is less than the range of motion of a normal joint, and less than with a semi-constrained hip prosthesis. The patient should be told that, although the constrained hip liner provides resistance to dislocation, it can dislocate if subjected to excessive loading. Once dislocated, additional surgery could be required to reduce the joint in many cases.
2. Wear of the components can occur and potentially lead to future complications, including dislocation, bone resorption and loosening, necessitating the removal and replacement of the prosthetic components.
3. The patient should be advised that the expected life of joint replacement components is difficult to estimate, and that many factors may contribute to the longevity of the prosthesis. The prosthesis is designed for restoration of mobility and reduction of pain, however device components cannot be expected to last indefinitely or to withstand the activity level and loads of normal healthy bone.
4. Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.
5. Patients should be instructed that significant reduction in the range of motion is inherent to the design characteristics of a constrained acetabular liner, and that activities that may force the joint to exceed those range of motion limits should be avoided.

MRI INFORMATION

Biomet® *Freedom* Constrained Liner System has not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only. Do Not Reuse. Do not resterilize. 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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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

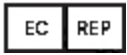


Batch code



FLAMMABLE

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