

Freedom® Constrained Liner

Surgical Technique



BIOMET®

Reaming and Sizing

Carefully ream the acetabulum to prepare for placement of the acetabular component.



Figure 1

Shell Insertion

Thread the acetabular inserter onto the selected acetabular component and place into the acetabulum (Figure 2). Impact the component, taking care to check for proper anatomic positioning.



Figure 2

Freedom® Trial Liner Insertion

Place the selected trial liner into the acetabular component, as shown in Figure 3. The trial will fit loosely around the rim tabs and will loosely engage the locking ring.



Figure 3

Biomet as the manufacturer of this device, does not practice medicine and does not recommend this device or technique. Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient.

Trialing with Freedom® Trial Heads

Determine the desired neck length and select the appropriate trial head. Locate the small line etch on the head; position this line marking in the most superior position (Figure 6). Reduce the joint by aligning the flat aspect of the head with the liner's mouth and place the joint through a full range of motion to ensure stability, checking that there is no early impingement (Figure 4).

Note: Never mix the implant components and the trial components to perform a trial reduction. Trials may become attached to the implant, and the process of forcing these components apart can irreparably damage the implant(s).



Figure 4

Freedom® Implant Insertion

Remove the black plug covering the mouth of the liner using the plug remover tool; discard this plug. Place the liner into the acetabular component (Figure 5). When satisfied with placement, use the Freedom® Liner impactor to seat the implant into the shell.



Figure 5

Freedom® 36mm Head Placement

Clean the femoral implant trunnion with a dry sponge. Before impacting the head on the trunnion, position the etched line on the head such that it is located in the most superior position and is aligned with the lateral aspect of the stem (Figure 6). Press the head onto the stem and double check that the etch is still in the most superior position. Fully seat the head on the neck with at least three firm mallet blows.



Figure 6

Reduction

Mobilize the leg so that the head is placed at the mouth of the liner. Flex and abduct the leg until the circumferential flat aspect of the head aligns with the liner mouth. Apply firm pressure straight into the liner until the head snaps into place. There will often be an audible “snap” when the head is fully reduced.

Ensure Full Stability

Before wound closure, re-check that the joint remains stable and will move throughout the anticipated range of motion without early impingement (Figure 7).

Note: If using the cemented all polyethylene cup, select the appropriate all polyethylene cup that corresponds to the inner diameter of the component being cemented into. For example, if cementing into a Regenerex® revision shell, there is a 10mm ID/OD mismatch. If a 60mm revision shell is used, the ID is 50mm; therefore a 50mm all polyethylene cup should be used.



Figure 7

Freedom® Constrained Liner

Implants

Product	Part Number	Trial Number	Description	Size
	11-107016	31-107016	Freedom® Const Head	-6mm
	11-107017	31-107017	Freedom® Const Head	-3mm
	11-107018	31-107018	Freedom® Const Head	Std.
	11-107019	31-107019	Freedom® Const Head	+3mm
	11-107020	31-107020	Freedom® Const Head	+6mm
	11-107021	31-107021	Freedom® Const Head	+9mm
	14-107016	31-117016	Freedom® 12/14 Const Head*	-6mm
	14-107017	31-117017	Freedom® 12/14 Const Head*	-3mm
	14-107018	31-117018	Freedom® 12/14 Const Head*	Std.
	14-107019	31-117019	Freedom® 12/14 Const Head*	+3mm
	14-107020	31-117020	Freedom® 12/14 Const Head*	+6mm
	14-107021	31-117021	Freedom® 12/14 Const Head*	+9mm
	11-107323	31-107323	Freedom® STD Face LNR	24
	11-107324	31-107324	Freedom® STD Face LNR	25
	11-107325	31-107325	Freedom® STD Face LNR	26
	11-107326	31-107326	Freedom® STD Face LNR	27
	11-107327	31-107327	Freedom® STD Face LNR	28
	11-107022	31-107022	Freedom® Const LNR +5	23
	11-107023	31-107023	Freedom® Const LNR +5	24
	11-107024	31-107024	Freedom® Const LNR +5	25
	11-107025	31-107025	Freedom® Const LNR +5	26
	11-107026	31-107026	Freedom® Const LNR +5	27
	11-107027	31-107027	Freedom® Const LNR +5	28
	11-107423	31-107423	Freedom® 10 DEG LNR	24
	11-107424	31-107424	Freedom® 10 DEG LNR	25
	11-107425	31-107425	Freedom® 10 DEG LNR	26
	11-107426	31-107426	Freedom® 10 DEG LNR	27
	11-107427	31-107427	Freedom® 10 DEG LNR	28
	11-107122	—	Freedom® All Poly Cup	50mm
	11-107123	—	Freedom® All Poly Cup	52mm
	11-107124	—	Freedom® All Poly Cup	54mm
	11-107125	—	Freedom® All Poly Cup	56mm
	11-107126	—	Freedom® All Poly Cup	58mm
	11-107127	—	Freedom® All Poly Cup	60mm
	11-107128	—	Freedom® All Poly Cup	62mm
	11-107222	31-107222	Freedom® Low Profile LNR	43
	11-107223	31-107223	Freedom® Low Profile LNR	44
	11-107224	31-107224	Freedom® Low Profile LNR	45
	11-107225	31-107225	Freedom® Low Profile LNR	46
	11-107226	31-107226	Freedom® Low Profile LNR	47
	11-107227	31-107227	Freedom® Low Profile LNR	48

* For use with 12/14 Taperloc® Stems.

Freedom™ Constrained Liner

Instruments

Product	Part Number	Description	Size
	31-107036	Freedom® Head Impactor	36mm
	31-107037	Freedom® RingLoc® LNR Impactor	—
	31-107039	Freedom® Cons LNR Plug Puller	—

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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.

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 activity, trauma and weight have been implicated with premature failure of the implant 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. 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.

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, 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.

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.

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.

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, 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.

Continued on next page.

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 semiconstrained 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.

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 after 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 USA, FAX: 574-372-3968

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