Introduction

The Reflection™ Microstable™ liner locking mechanism is a robust design that allows easy liner insertion and removal, and outstanding liner/shell stability. With the addition of an adapter ring, the Reflection shell provides the pull-out strength necessary for constrained liner applications.

The adapter ring is a three-piece construct packaged assembled on a Y-shaped holder that helps align the rings when being impacted into the shell.

The constrained liner is made of conventional, non-irradiated UHMWPE to retain the polyethylene material properties. The liner provides 4mm of lateralization.

The design of constrained liners involves a trade-off between head lever-out resistance and ROM. Typically, the higher the lever-out resistance, the smaller the ROM the device can achieve. The Reflection constrained liner was optimized to balance range of motion requirements with increased resistance to head lever-out.

The head lever-out of at least 270 inch-pounds for a 28mm head, is approximately 80% greater than a constrained device with multiple cases of re-dislocation reported in the literature and comparable to the smaller size tripolar constrained liners which have few reported re-dislocations. The adapter/liner assembly resists liner lever-out to levels of over 1300 inch-pounds. This is higher than all measurable lever-out loads of standard liners reported by Greenwald, et al, in the AAOS 1996 scientific exhibit.

Combined with Smith & Nephew circulo-trapezoidal neck, 87° of motion is achieved with a 28mm head. This exceeds reported measurements with a commonly used tripolar design.

Using the constrained liner in combination with a skirted head is not recommended. Skirted heads may reduce prosthetic ROM to clinically unacceptable levels.

Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors’ suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.
Surgical Technique

Constrained liners should be used only as a last resort, and only when all other available options to avoid dislocations have been exhausted. Such options include, but are not limited to, reorienting or using a different liner option (e.g. lateralized, anteverted etc), using a prosthesis with a larger head diameter, a stem with increased offset, or a head with increased length.

Shell preparation
When inserting a new Reflection shell: Prepare the acetabulum and insert the shell per respective surgical technique. The use of pegs or screws is recommended.

For a Reflection liner revision: Remove the existing liner using the liner removal tool. Remove the apex hole cover using a screwdriver

1.
Insert the appropriately sized Constrained Liner Adapter into the shell. The adapter should be placed into the liner lock mechanism. For ease of insertion and visual check, place the open end of the adapter rings over the removal slot on the shell or where best visibility of opening is possible.

2.
Insert the Alignment rod through the center of the adapter and screw into the apex hole in the shell. This may be performed by hand or using any of the standard Reflection 3.5mm hex screwdrivers.
3.
Select the respectively sized impactor and slide it over the end of the alignment rod. Place the legs of the impactor between the arms of the plastic holder of the adapter (see picture). Use a mallet to strike the platform on the impactor. When impacted sufficiently, the adapter device will be locked into the shell. When the ring is locked in place, the plastic holder is loose, and can be easily pulled from the adapter rings. If the plastic adapter is not loose, strike the impactor again and repeat check.

4.
Remove the plastic holder. This piece is disposable. At this point, the apex hole cover may be inserted into the shell.

5.
Insert the liner into the shell. Rotating the liner may be necessary to match up the anti-rotation splines of the liner with the inner adapter ring. When liner has been pushed as far as possible into the shell by hand, use the liner impactor tool to seat completely. After liner is assembled, visually check the liner lock ring to see if it has closed back together.
6. Place the retainer ring over the head of the femoral implant with the "tabs" facing away from the femur. Reduce the femoral implant head into the opening of the acetabular liner. Rotate the femur to check mobility of the head in the liner. After the head is in the liner, position the retainer ring tabs into the mating slots on the liner face. To find the slots, place the tabs onto the groove in the face and rotate the ring until they drop in the slots.

7. Once all tabs are started into the slots, push the retainer ring down until the tabs are seated fully. To seat all the way, the use of the horseshoe shaped retainer impactor may be desired. Place the retainer impactor around the neck of the femoral component and push on the retainer ring, using a mallet if needed. Use of other tools to push the impactor ring could cause damage, which could lead to ring fracture.
**Finished Assembly**

**Adapter Ring Assembly**
- A. Split Ring
- B. Inner Adapter Ring
- C. Liner Lock Ring

**Liner Assembly**
- D. Liner
- E. Constraining Ring
- F. Retaining Ring
## Catalog Information

### Implants

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### Instruments

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IMPORTANT MEDICAL INFORMATION
Warnings and Precautions
Reflection Constrained Liner Acetabular System

IMPORTANT NOTE
The Reflection Constrained Liner Acetabular System is designed for those total hip replacement patients who suffer from or are at risk for recurrent dislocations. The Reflection Constrained Liner Acetabular System 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 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 will be required to reduce the joint.

Patients should also be instructed that significant reduction in the range of motion is inherent to the design characteristic of a constrained acetabular liner, and activities that may force the joint to exceed those range of motion limits should be avoided.

MATERIALS
Acetabular shells and locking rings are manufactured from titanium alloy (Ti-6Al-4V). The acetabular liner and poly ring are manufactured from ultra high molecular weight polyethylene (UHMWPE). The adapter holder is manufactured from copolymer acetal resin.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomenon, in spite of the millions of implants in use.

DESCRIPTION OF SYSTEM
The Reflection Constrained Liner and Shell Construct is a multi-piece component made up of any Reflection Shell, the Constrained Liner Adapter and the Constrained Liner Construct. The Constrained Liner Adapter includes a plastic holder (disposed after adapter insertion) and locking rings that are inserted into the shell so that the shell can be used with the Constrained Liner. The Constrained Liner Construct includes the liner, poly ring and retaining ring. Therefore, the entire implanted Reflection Constrained Shell and Liner Construct includes the following: metal shell with locking rings in place and the liner, poly ring and retaining ring.

The Constrained Liner may be used with previously implanted femoral stems, femoral heads and acetabular shells as in a revision case, or it may be used in primary cases and implanted along with the shell, head and stem. Any Reflection shell may be utilized, provided it will accept a 28 mm metal femoral head. The Constrained Liner should not be used with ceramic femoral heads or skirted femoral heads of any material.

All implantable devices are designed for single use only.

Please see the package insert for the femoral stems and femoral heads for Warnings and Precautions for these devices.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS
The Reflection Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

Contraindications
1. Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately-sized implant, e.g.: a. blood supply limitations; b. insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and c. infections or other conditions which lead to increased bone resorption.
2. Mental or neurological conditions which tend to impair the patient’s ability or willingness to restrict activities.
3. Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
4. Skeletal immaturity.

Contraindications may be relative or absolute and must be carefully weighted against the patient’s entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others.

Conditions presenting increased risk of failure include: osteoporosis, metabolic disorders which may impair bone formation, and osteomalacia.

Possible Adverse Effects
1. Wear of the polyethylene articulating surfaces of acetabular components may occur. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop during or as a result of the surgical procedure and 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 as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondly, particles may also be generated by third-body particles lodged in the polyethylene articular surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions that follow. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocation or fracture of the locking ring may occur and may increase the risk for device dislocation. Periodic x-rays are recommended for close comparison with immediate postoperative conditions to detect evidence of ring disassociation or fracture. With evidence of ring disassociation or fracture, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered. In addition, the patient should be advised that ring disassociation or fracture may require additional surgery.
5. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, looseness of acetabular or femoral components, extraneous bone, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intrapelvic protrusion of acetabular component, femoral impingement, periarthritic calcification, and/or excessive reaming.

6. Fracture of the pelvis or femur: post-operative pelvic fractures are usually stress fractures. Femoral fractures are often caused by defects in the femoral cortex due to misdirected reaming, etc. Intraoperative fractures are usually associated with old congenital deformity, improper stem selection, improper broaching, and/or severe osteoporosis.

7. Infection, both acute post-operative wound infection and late deep wound sepsis.

8. Neuropathies; femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.

9. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.

10. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarthritic calcification with or without impediment to joint mobility can cause decreased range of motion.

11. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.

12. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement.

13. Damage to blood vessels.

14. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.

15. Delayed wound healing.

16. Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.

17. Failure of the porous coating/substrate interface or hydroxyapatite coating/porous coating bonding may result in bead separation delamination.

18. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Varus stem alignment may also be responsible.

WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible adverse effects including the risk of ring failure and device dislocations. The patient should 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 or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from different manufacturers. Additional Warnings and Precautions may be included in component literature.

Preoperative

1. Use extreme care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.

2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.

3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.

4. Surgical technique information is available upon request. The surgeon should be familiar with the technique. Refer to medical or manufacturer literature for specific product information.

5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.

Intraoperative

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in loosening, bending, cracking, or fracture of the component and/or bone.

2. Correct selection of the neck length and cup, and stem positioning, are important. Muscle looseness and/or malpositioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stresses which must be borne by the stem. The component should be firmly seated with the component insertion instruments.

3. Care should be taken not to scratch, bend or cut implant components during surgery for the reasons stated in Number One of the “Pre-Operative” section of “Warnings and Precautions.”

4. When using modular heads with sleeves and extended liners with the Reflection Constrained System, use caution and consider component malposition, component placement, and the effect on range of motion. Malposition of the Constrained Acetabular Component may cause impingement, premature dislocation, and revision.

5. Use only Reflection Liners with Reflection Shells.

6. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrhage. Do not place a screw in the center hole of the acetabular prosthesis. Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury. Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, or a new shell if necessary.

7. USE ONLY REFLECTION TITANIUM BONE SCREWS, UNIVERSAL CANCELLOUS BONE SCREWS, TAPERED PEGS, AND HOLE COVERS with the Reflection Acetabular Component. The Reflection InterFit and the Reflection For Screws Only (FSO) shells accept Universal Cancellous, Reflection screws, and tapered screw-hole covers, not pegs. Tapered pegs can only be used with Reflection V Shells. The threaded center hole in Reflection Shells only accepts the threaded hole cover, not screws or pegs. The InterFit threaded hole cover is only for use with Reflection InterFit. The Reflection threaded hole cover can be used with both Reflection and InterFit shells. Refer to product literature for proper adjunctive fixation and hole cover usage.
8. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue does not interfere with the shell/liner interface. Modular components must be assembled securely to prevent disassociation. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.

9. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.

10. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.

11. If the head is removed from a femoral component that will be left in place at revision surgery, a metal head must be used.

12. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of looseness, etc. and replaced if necessary. The head/neck component should be changed only when clinically necessary.

13. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture of these components.

14. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is often very small and straight and may require an extra-small straight femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that the true acetabulum is rudimentary and shallow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.

15. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of the medial acetabular wall, femur, or greater trochanter.

16. Revision procedures for previous arthroplasty, Girdlestone, etc., are technically demanding and difficult to exercise. Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, or improper positioning of components. Postoperative instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.

17. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked for early contact or instability.

18. Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, and/or dislocation.

19. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.

20. To correctly position the metallic locking ring that is a part of the Constrained Liner assembly, surgeons should consult the Reflection Constrained Liner System surgical technique for appropriate device assembly.

Postoperative
1. Postoperative directions and warnings to patients by physicians, and patient care, are extremely important. Gradual weight bearing is begun after surgery in ordinary total hip arthroplasty. However, with trochanter osteotomy or certain complex cases, weight-bearing status should be individualized with the non or partial weight-bearing period extended.

2. Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip.

3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, and clothing, similar activities, precautions should be taken to avoid placing excessive load on the operative part of the body.

4. Postoperative therapy should be structured to regain muscle strength around the hip and a gradual increase of activities.

5. Periodic x-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.

6. Prophylactic antibiotics should be recommended to the patient similar to those suggested by the American Heart Association for conditions or situations that may result in bacteremia.

7. If the Constrained Liner dislocates, closed reduction is not possible. Patients should be advised that if the Constrained Liner dislocates, additional surgery will be required.

PACKAGING AND LABELING
Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION
Implants and the plastic adapter holder are supplied sterile and have been packaged in protective trays. Other instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

If the sterile barrier has been broken and the components have not contacted blood, the components may be resterilized using ethylene oxide gas. If the components have contacted blood, they may not be reused.

The following parameters are recommended as starting points for cycle validation by the health care facility:

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<th>Sterilant</th>
<th>Temp.</th>
<th>Humidity</th>
<th>Maximum Pressure</th>
<th>Concentration</th>
<th>Exposure Time</th>
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<tr>
<td>100% EtO</td>
<td>111°F (55°C)</td>
<td>40-80% (70% Target)</td>
<td>10 PSI (689 millibar)</td>
<td>725 mg/l</td>
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Suggested initial starting point for aeration validation is 12 hours at 120°F (49°C) with power aeration. Consult aerator manufacturer for more specific instructions.

INFORMATION
For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls. Smith & Nephew, Inc., Orthopaedic Division, 1450 Brooks Road, Memphis, Tennessee, U.S.A.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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