

## Constrained liner





# Design surgeon

Smith & Nephew thanks the following surgeons for their participation as part of the R3° system design team:

Robert Barrack, MD  
St. Louis, Missouri

Robert Bourne, MD  
London Health Sciences Center  
London, Ontario, Canada

Jonathan Garino, MD  
University of Pennsylvania  
School of Medicine  
Philadelphia, Pennsylvania

Wayne M. Goldstein, MD  
Clinical Professor of Orthopaedics  
University of Illinois at Chicago  
Illinois Bone and Joint Institute  
Chicago, Illinois

Richard Kyle, MD  
Minneapolis, Minnesota

Stephen J. McMahon, MB, BS, FRACS(Orth), FA(Orth)A  
Senior Lecturer Monash University  
Malabar Orthopaedic Clinic  
Melbourne, Australia

John L. Masonis, MD  
OrthoCarolina  
Hip & Knee Center  
Charlotte, North Carolina

Henrik Malchau, MD  
Associate Professor, Harvard Medical School  
Co-Director, The Harris Orthopaedic Biomechanics  
and Biomaterials Laboratory  
Massachusetts General Hospital  
Boston, Massachusetts

Michael Ries, MD  
University of California  
San Francisco, California

Cecil Rorabeck, MD  
Professor of Orthopaedic Surgery  
University of Western Ontario  
London, Ontario, Canada

**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.

# Short technique



1. Liner impaction



2. Reduce hip

In the event that dislocation is required, the head removal tool may be used. Fully insert the tip of the appropriated sized removal tool inside the inner bearing (around the femoral head) and hold until the femoral head is dislocated.



3. Removal tool positioning



4. Femoral head removal

## R3<sup>◊</sup> constrained liner product overview

Innovation, a fundamental Smith & Nephew principle is again displayed in the R3<sup>◊</sup> Acetabular System. The R3 acetabular cup is designed to accommodate multiple bearing options and STIKTITE<sup>◊</sup> provides a porous coating designed to enhance bony in-growth. The system will allow you to go from resurfacing to a constrained liner without removing a well fixed shell. The R3 polyethylene liner locking mechanism is a robust design that allows for easy liner insertion and removal, and outstanding liner/shell stability.

The R3 constrained liner is designed for total hip replacement patients who suffer from or are at risk for recurrent dislocations. The R3 constrained liner option consists of a bipolar bearing which articulates with a captured outer polyethylene liner. This will allow for motion at two interfaces; the femoral head with the bipolar and the bipolar with the outer liner.

The design of constrained liners involves a trade-off between head lever-out resistance and range of motion (ROM). Typically, the higher the lever-out resistance, the smaller the ROM the device can achieve. The R3 constrained liner is optimized to balance range of motion requirements with increased resistance to head lever-out.<sup>1</sup>

Patients should 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.

The constrained liner is made of conventional, non-irradiated UHMWPE to retain the polyethylene material properties. Combined with the Smith & Nephew circuloapezoidal neck, a range of motion between 82° to 102° can be achieved depending on the head size used.

## Product overview

The R3° constrained liner 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 may be required to reduce the joint.

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

R3 Constrained Liner ROM chart

Liner	ROM
52	82°
54	82°
56	90°
58	90°
60	96°
62	96°
64	102°
66-70	102°

# R3<sup>◇</sup> constrained liner surgical technique

Constrained liners should only be used 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, using a prosthesis with a larger head diameter, a stem with increased offset, or a head with increased length.

## Surgical tip:

Refer to the Smith & Nephew RENOVATION<sup>®</sup> implant removal system reference guide for information on removing a well fixed shell.

## Shell preparation

When inserting a new R3 shell; prepare the acetabulum and insert the shell as instructed in the R3 surgical technique. The use of screws is recommended due to lack of bone in-growth and the stability they add to the construct.

To remove a R3 liner: Remove the existing liner using the liner removal tool. Ensure the shell is free and clear of debris prior to inserting a new liner into the shell.

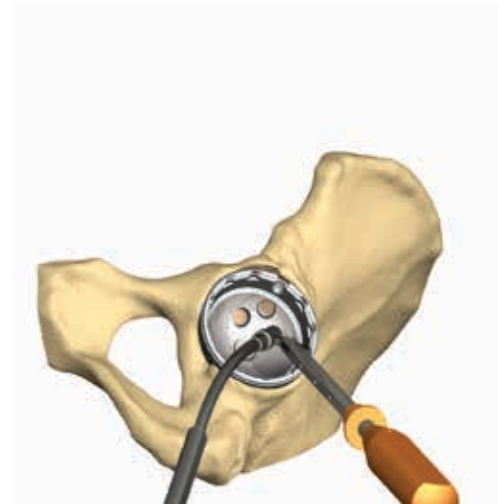


## Acetabular screw insertion

Screw fixation is simple, fast and the most common method of assuring additional fixation. Acetabular screws work in compression, which allows the shell to fully seat in the acetabular cavity.

For screw fixation, each screw hole must be predrilled. Using the variable angle drill guide, adjust the angle of the tip to align with the selected screw hole and **press firmly in the shell**. After drilling the hole, use the depth gauge to verify appropriate screw length(s).

Use the screw forceps to hold the screw. Attach the ball-joint or flexible screwdriver shaft to the end of the screw. Then introduce the screw into the hole and screw it into place using the ratcheting screwdriver handle. Make sure the screw is fully seated within the screw hole so that it will not impinge on the acetabular shell/liner.



# Constrained liner insertion

Determine the appropriate size constrained liner and internal femoral head size that will be used. The R3° constrained liners are designed to accommodate one liner per shell size. The R3 constrained liner is fully assembled when removed from the sterile packaging. A head exchange will most likely be necessary.

Insert the R3 constrained liner into the acetabular component by hand and rotate until the tabs on the liner align with the scallops in the shell. The locking ring is designed to fit into the groove around the rim of the R3 shell.

Assemble the appropriate size constrained liner impactor head to R3 shell impactor and then position tip inside liner.



Impact until lock ring has engaged in the shell.



Once the constrained liner is in place do not perform a trial reduction as the trial head may be difficult to remove.

If a new femoral head is used, lock onto the stem using the femoral head impactor.

Minimal force is required to reduce the hip; however, joint laxity among other patient factors may have an effect.

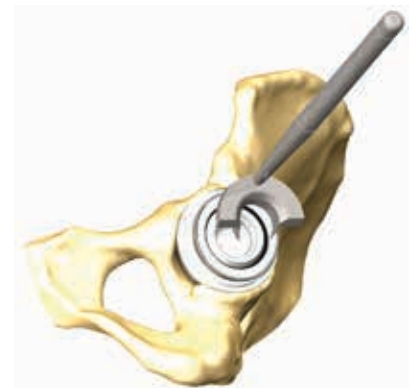




Reduce the hip. Avoid aggressive range of motion evaluation as it could compromise implant function and may result in unintentional dislocation, extended OR time and/or adverse patient effects.



In the event that dislocation is required, the head removal tool may be used. Fully insert the tip of the appropriate sized removal tool inside the inner bearing (around the femoral head) and hold until the femoral head is dislocated.



## R3<sup>◇</sup> constrained liner sizing

Shell OD in mm	Bipolar OD in mm	Bipolar ID in mm	Outer poly thickness in mm	Outer spherical diameter in mm
52	38	22	4	46.5
54	38	22	5	48.5
56	40	22	5	50.5
58	40	22	6	52.5
60	44	28	5	54.5
62	44	28	6	56.5
64	48	28	5	58.5
66-70	48	28	6	60.5



# Catalog

7133-9152	R3° Constrained Acetabular Liner 52mm
7133-9154	R3 Constrained Acetabular Liner 54mm
7133-9156	R3 Constrained Acetabular Liner 56mm
7133-9158	R3 Constrained Acetabular Liner 58mm
7133-9160	R3 Constrained Acetabular Liner 60mm
7133-9162	R3 Constrained Acetabular Liner 62mm
7133-9164	R3 Constrained Acetabular Liner 64mm
7133-9166	R3 Constrained Acetabular Liner 66-70mm

7136-2014	Constrained Liner Instrument Tray
7136-2015	R3 Constrained Liner 22mm Impactor Head
7136-2016	R3 Constrained Liner 28mm Impactor Head
7136-2017	R3 Constrained Liner Head Removal Tool 22
7136-2018	R3 Constrained Liner Head Removal Tool 28
7136-4009	Femoral Head Impactor

## References

- 1 Our internal test reports show an inner head shuck out of 275.7 in-lb for a 22mm femoral head and an outer head shuck out of 638.6 in-lb for a 38mm bipolar head. The schuck out values will increase for the larger size shells.

# R3° Constrained Liner Acetabular System

## Important Medical Information

### R3° Constrained Liner Acetabular System

#### Important Note

The R3 Constrained Liner Acetabular System is designed for those total hip replacement patients who suffer from or are at risk for recurrent dislocations. The R3 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, locking ring and outer reinforcement ring are manufactured from titanium alloy (Ti-6Al-4V). The bipolar head is manufactured from cobalt chromium alloy. The acetabular liners and finger trap ring are manufactured from conventional ultra high molecular weight polyethylene (UHMWPE).

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 R3 Constrained Liner and Shell Construct is a multi-piece component made up of any R3 Shell and the Constrained Liner Construct. The Constrained Liner Construct includes a bipolar bearing which articulates with a captured outer polyethylene liner, locking ring and outer reinforcement 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. Constrained liner only to be used with well in-grown shell or fresh shell secured with an adequate number of bone screws. The acetabular shell should be sufficiently supported by quality bone, resulting in adequate fixation. Poor fixation may contribute to early revision. Component malposition and/or impingement are potential causes of recurrent instability in constrained acetabular components and may lead to device failure. Any R3 shell may be utilized, provided it will accept a 22 or 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.

#### References

1. Su EP, Pellicci PM. The Role of Constrained Liners in Total Hip Arthroplasty. Clin Orthop. 2004 March, 420:122-129.
2. Guyen O, Lewallen DG, Cabanela ME. Modes of Failure of Osteonics Constrained Tripolar Implants: A Retrospective Analysis of Forty-Three Failed Implants. J Bone Joint Surg Am. 2008;90:1553-60.

#### Indications, Contraindications, and Adverse Effects

The R3 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 weighed 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 reinforcement ring 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, periarticular 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, periarticular 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 hydroxylapatite 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, device dislocations and component fracture. 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. Patients should be informed of the limited range of motion associated with constrained liner usage. Activities of daily living may need to be modified to avoid inducing impingement, which may cause dislocation, component overload, or the need for revision surgery.

### 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. Single use devices should not be reused due to risks of breakage, failure or patient infection.

### 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 R3 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 R3 Liners with R3 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 SPHERICAL HEAD TITANIUM BONE SCREWS, UNIVERSAL CANCELLOUS BONE SCREWS AND R3 SCREW HOLE COVERS with the R3 Acetabular Component. The threaded center hole in R3 Shells only accepts the threaded hole cover, not screws. The REFLECTION threaded hole cover can be used with both R3 and REFLECTION 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 and polyethylene locking/reinforcement rings, surgeons should consult the manufacturer's instructions for appropriate device assembly.
21. A locking/reinforcement ring that is placed incorrectly may have a reduced service life.
22. Locking/reinforcement ring failure, which may be due to impingement, fatigue, and/or wear, increases the probability of dislocation.
23. Avoid aggressive range of motion evaluation as it could compromise implant function and may result in unintentional dislocation, extended OR time, and/or adverse patient effects.

#### 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, and 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.

#### Magnetic Resonance Imaging (MRI) Safety

The R3 Constrained Liner Acetabular System has not been evaluated for safety and compatibility in the MR environment. The R3 Constrained Liner Acetabular System has not been tested for heating or migration in the MR environment.

#### Packaging and Labeling

Implants should only be accepted by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

#### Sterilization

Implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10<sup>-6</sup>. Implant components are supplied in protective packaging. Inspect packages for punctures or other damage prior to surgery. The method of sterilization is noted on the package label.

DO NOT REUSE OR RESTERILIZE implant components or single use disposable instruments. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components. If not specifically labeled sterile, instruments are supplied non-sterile and must be cleaned and sterilized prior to surgery. Please see also the document, "Recommendations for decontamination and sterilization of Smith & Nephew Orthopaedic devices", which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

Recommended Steam Sterilization Cycle Parameters (Reusable Instruments Only, Not Poly Liners)

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes and a minimum vacuum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle (Reusable instruments only): 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134° C (273°F) for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010).

Containment devices should be wrapped with a central supply wrap (CSR) or placed in a reusable rigid container for sterilization. Note to US Customers: FDA cleared sterilizers and wraps are to be used in your sterilization processes.

#### Retrieval and Analysis of Removed Implants

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of bloodborne pathogens.

If the implant will be returned to Smith & Nephew, Inc. for analysis, contact Customer Service using the phone numbers outlined in the Information section.

#### 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.

Manufacturing facilities and EC representative:

Smith & Nephew Inc.  
1450 Brooks Road  
Memphis, TN 38116 U.S.A.  
Tel.: 901-396-2121

Smith & Nephew Orthopaedics GmbH  
Alemannenstrasse 14  
78532 Tuttlingen, Germany  
Tel.: 07462/208-0  
Fax: 07462/208-135

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

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81074993 Rev. A 2011-09  0086



**Orthopaedics**

Smith & Nephew, Inc.  
7135 Goodlett Farms Parkway  
Cordova, TN 38016  
USA

[www.smith-nephew.com](http://www.smith-nephew.com)

Telephone: 1-901-396-2121  
Information: 1-800-821-5700  
Orders and Inquiries: 1-800-238-7538

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