



**TRILOGY®
ACETABULAR
SYSTEM
CONSTRAINED
LINER**

Surgical
Technique



zimmer
Confidence in your hands™

Postoperative Care, Indications, Contraindications and Warnings

DESCRIPTION

The *Trilogy* Acetabular System Constrained Liner is a device consisting of a liner and reinforcing ring. The ultra-high molecular-weight polyethylene (UHMWPE) liner fits into the *Trilogy* Acetabular System metal shell and articulates with metal femoral heads manufactured by Zimmer. The articular surface opening of the *Trilogy* Constrained Liner is reduced slightly to allow for mechanical capture of the femoral head. The liner can be used with all *Trilogy* Acetabular System shell designs.

The reinforcing ring is made from *Titanium*® Ti-6Al-4V Alloy. This ring fits into a groove on the outer surface of the liner to reinforce the capture of the femoral head within the liner.

INDICATIONS

The *Trilogy* Acetabular System Constrained Liner is indicated for either cemented or noncemented use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

CONTRAINDICATIONS

Bone necrosis induced by radiation can occur as the result of therapeutic exposure to >35Gy for the treatment of cancer. Osteoradionecrosis of the acetabulum is a relative contraindication to total hip joint replacement because of the likelihood of failure of the acetabular implant due to poor bone stock. In cases where hip arthroplasty is necessary when pelvic radiotherapy has previously occurred, use of protrusion rings, bone graft harvested from outside the zones of irradiation, and bone cement may be required to minimize the risk of subsequent failure of the acetabular implant.

The *Trilogy* Constrained Liner should not be used with skirted femoral heads. The skirt will reduce the range of motion, increasing the possibility of impingement and subsequent dislocation of the device.

WARNINGS

This product should only be used with a well-fixed *Trilogy* Acetabular Shell. Ancillary screw fixation of the shell is highly recommended to assist in maintaining fixation at the shell/bone interface.

Where there is loss of, or insufficient acetabular bone stock, bone grafting or other adjunctive reinforcement procedures to provide socket support and cup containment are recommended.

Closed reduction of this device is not possible. Patients should be made aware that treatment of device dislocation will require additional surgery.

Do not use the *Trilogy* Acetabular System Constrained Liner with components of other manufacturers. Combining products of different manufacturers may lead to premature wear or

failure of the device.

The *Trilogy* metal shell and constrained acetabular liner require alignment to prevent impingement of the liner and the femoral neck. Careful attention to position and range of motion should be observed. Impingement may lead to dislocation of the femoral head from the constrained liner.

Assemble the reinforcing ring on the constrained acetabular liner only once. If the device is not assembled correctly, it should be removed and replaced with a new liner and reinforcing ring.

Do not implant the *Trilogy* Constrained Liner without the reinforcing ring assembled. The ring provides additional constraint of the polyethylene liner with femoral head capture.

Ring failure has been reported for similar devices. Proper monitoring should be conducted. If ring failure or dissociation is observed, additional surgery may be required.

PRECAUTIONS

To avoid impingement, do not use the constrained liner with any femoral component or femoral head where the passive range of motion is restricted to less than 90°. These include skirted femoral heads for 6 degree and 12/14 neck tapered stems, as well as the 6 degree femoral head designated "short."

Transient bacteremia occurs after dental manipulation, endoscopic examinations, and other minor surgical procedures. To prevent late infection at the implant site, many orthopaedic surgeons advise the use of antibiotic prophylaxis before and after such procedures for their patients with total joint implants.¹

Do not use implant components (femoral head, acetabular liner) to perform a trial reduction of the hip. Mate provisional (trial) femoral heads with provisional acetabular liners only. Contact of the femoral head implant with the provisional acetabular liner can result in abrasion of the femoral head, and contact of the implant acetabular liner with the provisional femoral head can result in abrasion of the implant acetabular liner.

It is important that components be at room temperature before assembly and implantation. Components that are significantly warmer than ambient conditions (e.g., from storage in a warm environment) may be difficult to assemble properly.

Never reuse an implant. Although it may appear undamaged, previous stresses may have created imperfections that could reduce the service life of the implant.

To correctly position the metallic locking ring, surgeons should consult the manufacturer's instructions for appropriate device assembly.

Postoperative Care, Indications, Contraindications and Warnings

ADVERSE EFFECTS

Early or late loosening of total hip replacement components has occurred. Early mechanical loosening may result from defective fixation (suboptimal cementing technique) or latent infection; late loosening from biological complications, or mechanical problems (localized high stresses).

Heterotopic bone formation is a well-recognized sequel to total hip arthroplasty.² In severe cases, it leads to ankylosis of the joint which causes reduced mobility. The following patient categories are reported in the literature to be at high risk to develop this complication:

1. Patients who already have ectopic bone on the ipsilateral or contralateral hip.
2. Patients suffering from ankylosing spondylitis or Forestier's disease.
3. Patients undergoing revision surgery or surface replacement.
4. Male osteoarthritic patients, especially those with hypertrophy at the hip or spine.
5. Trauma patients, e.g., those with concomitant femoral fractures and acetabular involvement.

Dislocation and migration have been reported resulting from improper positioning of the implant components. Muscle and fibrous tissue laxity can also contribute to these conditions. Bony impingement at extremes of motion has also been implicated in hip dislocations.

The following complications have been reported from transacetabular pelvic penetration of bone cement or screw threads into the pelvic cavity:

- Iliacus hematoma
- Bladder fistula
- External iliac artery thrombosis
- Intrapelvic hemorrhage resulting in death

Any orthopaedic implant may fail, loosen, or fracture. In addition, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in the literature that a variety of metals, polymers, chemicals, and other materials utilized with orthopaedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopaedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long-term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive

system, and others) to bone or seeded to these locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.³

2. Implantation of foreign material in tissues can elicit an inflammatory reaction. Literature suggests that wear debris (including metal, polyethylene, ceramic and cement particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening.⁴ While formation of wear debris may be an inevitable consequence of motion at articulating implant surfaces, optimal technique for cementing or fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or cement/prosthesis interface. The patient should be informed of the possibility of implant loosening as a result of wear debris.
3. Metal sensitivity has been reported following exposure to orthopaedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopaedic grade stainless steel and cobalt-chrome alloys.⁵ Titanium and its alloys (such as Titanium Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

PATIENT COUNSELING INFORMATION

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

REFERENCES

1. Nelson, J. Phillip, et al., Prophylactic Antimicrobial Coverage in Arthroplasty Patients, *JBJS*, 72A(1);1,1990.
2. Stillwell, W.T., *The Art of Total Hip Arthroplasty*, Grune & Stratton, Inc.,363-370,1987.
3. Sharkness, C.M., Acosta, S.K., Moore, R.M., et al., Metallic Orthopaedic Implants and Their Possible Association with Cancer, *Journal of Long - Term Effects of Medical Implants*, 3(3):237-249,1993.
4. American Society for Testing and Materials, ASTM Committee F-4, Symposium on Biocompatibility of Particulate Implant Materials, Oct 31, 1990.
5. Fisher, AA., *Contact Dermatitis*, 3rd Ed., Lea and Febiger, 338-367, 1986.

1 LINER REMOVAL

Remove the existing polyethylene liner, taking care not to damage the *Trilogy* shell or locking ring. Use the Disassembly Device to open the ring while at the same time using the Liner Extractor to grip and lift the liner out of the shell.



2 SHELL ASSESSMENT

Assess the shell locking ring. The ring should float freely inside the shell with the two tabs protruding through the locking ring window. The ring serves to lock the liner in place. If it is damaged in such a way that it does not float freely inside the shell, remove the ring and put a new one in place (Step 3).

If the shell is damaged, an alternative surgery should be considered.



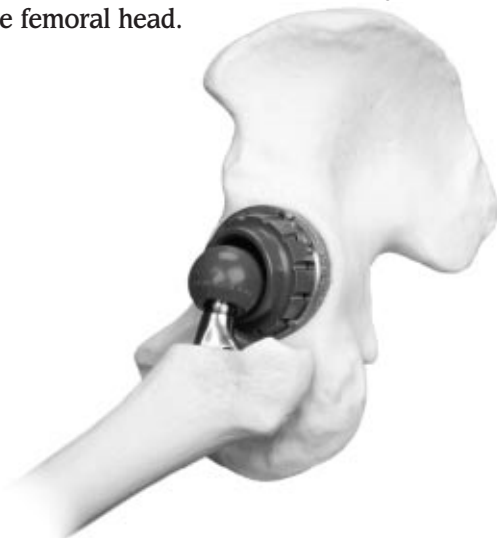
5 TRIAL REDUCTION

Select the liner provisional that matches the implanted shell ID and place it in the shell. Check to be certain that all soft tissue has been cleared from the shell periphery. Orient the provisional to the appropriate position, providing head coverage and dislocation resistance.



Reduce the hip and assess complete range of motion, particularly with respect to obstruction or impingement.

Note: At this point, constraint has not yet been placed on the femoral head.



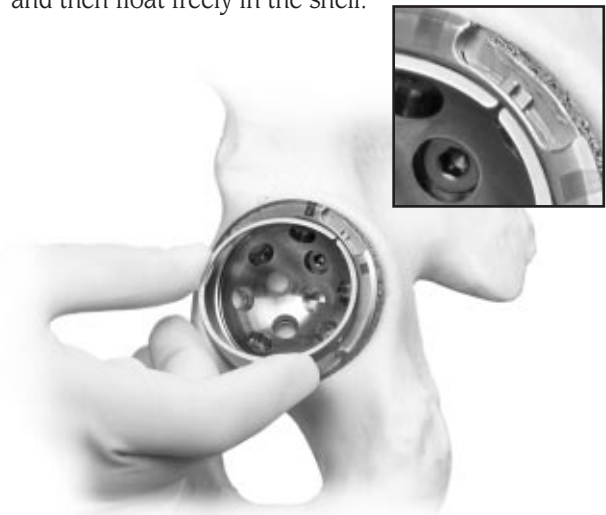
Note: The Constrained Liner is part of a total hip prosthesis and must be used only with a stable Zimmer femoral component and a well-fixed *Trilogy* acetabular shell.

3 LOCKING RING REPLACEMENT (IF REQUIRED)

To remove the old ring, push the ring to the side of the shell and grab the exposed portion on the opposite side of the shell. A firm and steady grip is required.



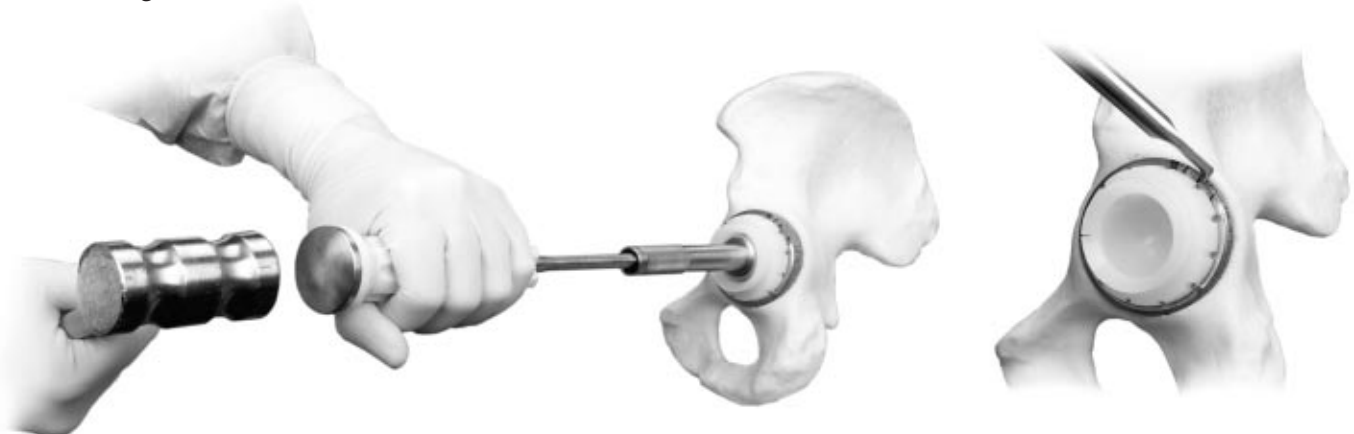
To insert a new ring, first insert the tabs of the ring into the locking ring window. Then, press the ring into place. When properly seated, the ring will first pop into place and then float freely in the shell.



6 LINER INSERTION

Remove the liner provisional and, after cleaning and drying the shell interior, place the *Trilogy* Constrained Liner into the shell with the 10° face in the same orientation as previously determined with the liner provisional. Use a 28mm or smaller Mechanical Liner Inserter to seat the liner within the shell. **Note: Do not use the regular 32mm head attachment as it may catch inside the constraining internal diameter.**

The Constrained Liner is fully seated when the tabs have closed back to their original position. When the tabs have closed, the locking ring can move inside the shell. This can be checked by moving the tabs with a blunt instrument.

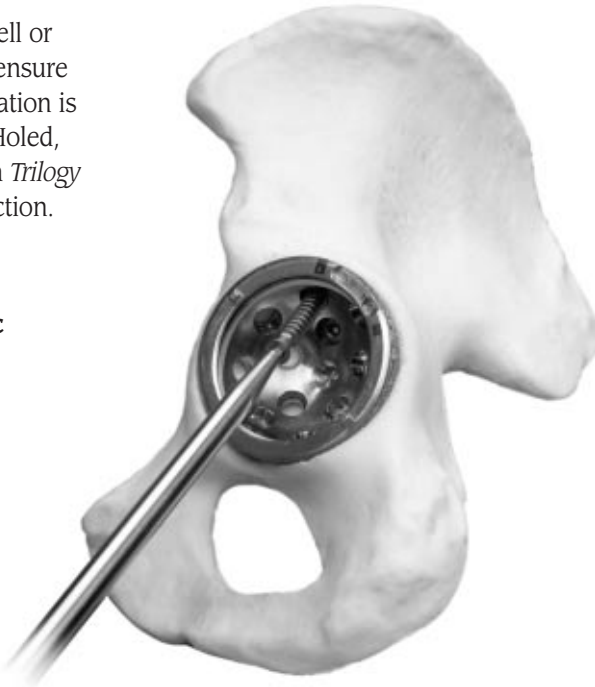


4

SUPPLEMENTAL FIXATION

Remove any membranes from inside the shell or screw holes. Clean and inspect the shell to ensure its integrity and stability. If supplemental fixation is desired for the *Trilogy* Cluster-Holed, Multi-Holed, or Uni-Holed Shells, insert 4.5mm or 6.5mm *Trilogy* Bone Screws before performing a trial reduction.

Warning: Avoid placing screws in the anterior superior or anterior inferior quadrants to protect against neurologic and vascular injury.



7

IMPLANT ASSEMBLY

To assemble the Constrained Liner, place the metal reinforcing ring over the head of the femoral component with the ring's upraised rim closest to the face of the acetabular liner and shell.

Ease the femoral head into the Constrained Liner; some version may be required. Then, move the reinforcing ring, in line with the femoral neck, toward the liner and shell until the ring locks in place.

Warning: The reinforcing ring should only be assembled with the Constrained Liner once to avoid damaging the components.

Ring must be on with rim toward liner before reduction.



8

IMPLANT DISASSEMBLY (IF REQUIRED)

A blunt osteotome or similar instrument can be used to remove the ring from the liner. This need might occur in revision cases where a *Trilogy* Constrained Liner is already in place, or if an assembly error occurs. If a Constrained Liner is still preferred, select and implant a new liner and reinforcing ring.



TRILOGY ACETABULAR SYSTEM CONSTRAINED LINER



REVISION SURGERY WITH THE TRILOGY CONSTRAINED LINER

- Provides a revision surgery option that does not require removal of the shell.
- Fits within a *Trilogy* Acetabular Shell to provide additional constraint of the femoral head within the acetabulum for patients at high risk of dislocation.
- Partially slit design with an uninterrupted inner diameter and *Tivanium*® Ti-6Al-4V Alloy reinforcing ring for increased stability.
- Designed with a 32mm ID, 10° oblique face, and built-in liner offset for additional stability.
- Liner can be rotated to position head coverage opposite the actual or anticipated instability.
- Size range from 50mm-80mm OD.

ORDER INFORMATION

CONSTRAINED LINERS (Includes Reinforcing Ring)

Cat. No.	Description
6154-00-32	Constrained Liner Set (Set includes all items listed below)
6154-50-32	50/52/54mm OD x 32mm ID
6154-56-32	56mm OD x 32mm ID
6154-58-32	58mm OD x 32mm ID
6154-60-32	60mm OD x 32mm ID
6154-62-32	62mm OD x 32mm ID
6154-64-32	64mm OD x 32mm ID
6154-66-32	66mm OD x 32mm ID
6154-68-32	68mm OD x 32mm ID
6154-70-32	70mm OD x 32mm ID
6154-72-32	72mm OD x 32mm ID
6154-74-32	74mm OD x 32mm ID
6154-76-32	76mm OD x 32mm ID
6154-78-32	78mm OD x 32mm ID
6154-80-32	80mm OD x 32mm ID

CONSTRAINED PROVISIONALS

Cat. No.	Description
6164-00-32	Constrained Provisional Liner Set (Set includes all provisionals listed below)
6164-50-32	50/52/54mm OD x 32mm ID
6164-56-32	56mm OD x 32mm ID
6164-58-32	58mm OD x 32mm ID
6164-60-32	60mm OD x 32mm ID
6164-62-32	62mm OD x 32mm ID
6164-64-32	64mm OD x 32mm ID
6164-66-32	66mm OD x 32mm ID
6164-68-32	68mm OD x 32mm ID
6164-70-32	70mm OD x 32mm ID
6164-72-32	72mm OD x 32mm ID
6164-74-32	74mm OD x 32mm ID
6164-76-32	76mm OD x 32mm ID
6164-78-32	78mm OD x 32mm ID
6164-80-32	80mm OD x 32mm ID
6260-93	Provisional Case (includes base and lid)

TRILOGY BONE SCREWS

Cat. No.	Description
6250-45-15	Bone Screw 4.5mm x 15mm, Self-Tap
6250-45-20	Bone Screw 4.5mm x 20mm, Self-Tap
6250-45-25	Bone Screw 4.5mm x 25mm, Self-Tap
6250-45-30	Bone Screw 4.5mm x 30mm, Self-Tap
6250-45-35	Bone Screw 4.5mm x 35mm, Self-Tap
6250-45-40	Bone Screw 4.5mm x 40mm, Self-Tap
6250-45-50	Bone Screw 4.5mm x 50mm, Self-Tap
6250-45-60	Bone Screw 4.5mm x 60mm, Self-Tap
6250-65-15	Bone Screw 6.5mm x 15mm, Self-Tap
6250-65-20	Bone Screw 6.5mm x 20mm, Self-Tap
6250-65-25	Bone Screw 6.5mm x 25mm, Self-Tap
6250-65-30	Bone Screw 6.5mm x 30mm, Self-Tap
6250-65-35	Bone Screw 6.5mm x 35mm, Self-Tap
6250-65-40	Bone Screw 6.5mm x 40mm, Self-Tap
6250-65-50	Bone Screw 6.5mm x 50mm, Self-Tap
6250-65-60	Bone Screw 6.5mm x 60mm, Self-Tap

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

TRILOGY HOLED INSTRUMENTS

Cat. No.	Description
6260-99-02	Trilogy Holed Instrument Set (Set includes all items listed below)
6260-85-01	Case (includes Base and Lid)
6260-02	Flex Shaft with Modular Connector
6260-03-01	Drill Bit, 15mm
6260-03-02	Drill Bit, 30mm
6260-03-03	Drill Bit, 45mm
6260-06	Drill Guide
6260-07-01	Tap, 4.5mm
6260-07-02	Tap, 6.5mm
6260-08-01	Tap Guide, 4.5mm
6260-08-02	Tap Guide, 6.5mm
6260-10	Tap Handle
6260-13	Screw Holding Forceps, 15°
6260-14	Screw Holding Forceps, 45°
6260-24	Straight Screwdriver
6260-25	Universal Screwdriver
6260-26	Modular Universal Handle
6611-98	Depth Gauge

LINER INSERTER

Cat. No.	Description
6260-17-28	Mechanical Liner Inserter

LINER REMOVAL INSTRUMENTS

(Included in Trilogy Non-Holed Instrument Set – 6260-99-01)

Cat. No.	Description
6260-30-01	Disassembly Device
6260-35-01	Liner Extractor
6260-40	Liner Elevator



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Please refer to the package inserts for complete product information including contraindications, warnings, precautions, and adverse effects.

Contact your Zimmer Representative or visit us at www.zimmer.com